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Ullrich, Jr. et al.

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(45) **Date of Patent: Oct. 22, 2013**

(54) **ENDPLATE-PRESERVING SPINAL IMPLANT WITH AN INTEGRATION PLATE HAVING A ROUGHENED SURFACE TOPOGRAPHY**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61F 2/44 (2006.01)

(52) **U.S. Cl.**
USPC **623/17.16**; 623/17.11

(58) **Field of Classification Search**
USPC 623/17.11–17.16
See application file for complete search history.

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Assistant Examiner — Julianna N Harvey
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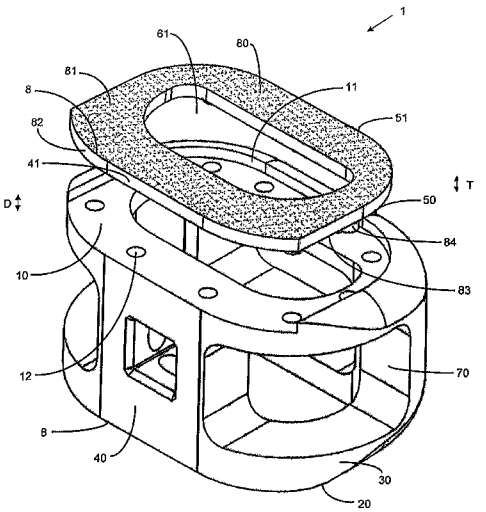
(57) **ABSTRACT**

An interbody spinal implant including a body having a top surface, a bottom surface, opposing lateral sides, opposing anterior and posterior portions, a substantially hollow center, and single vertical aperture, as well as an integration plate having a roughened surface topography on its top surface.

20 Claims, 33 Drawing Sheets



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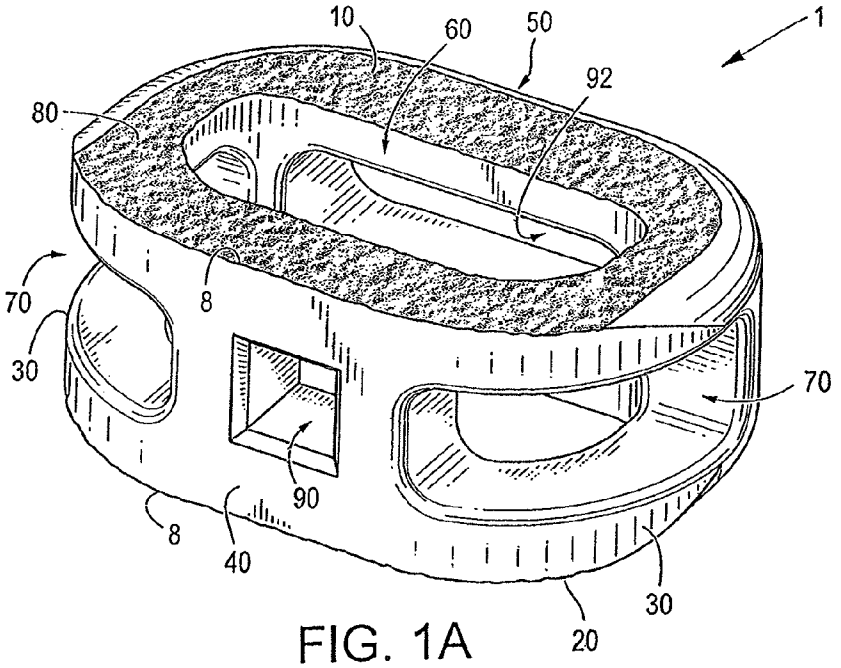

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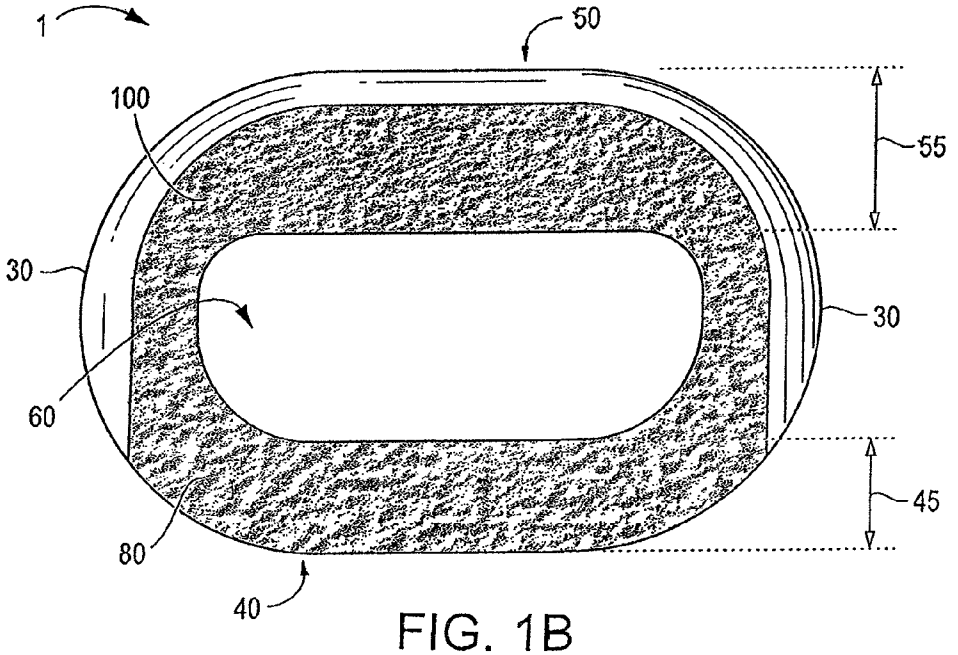

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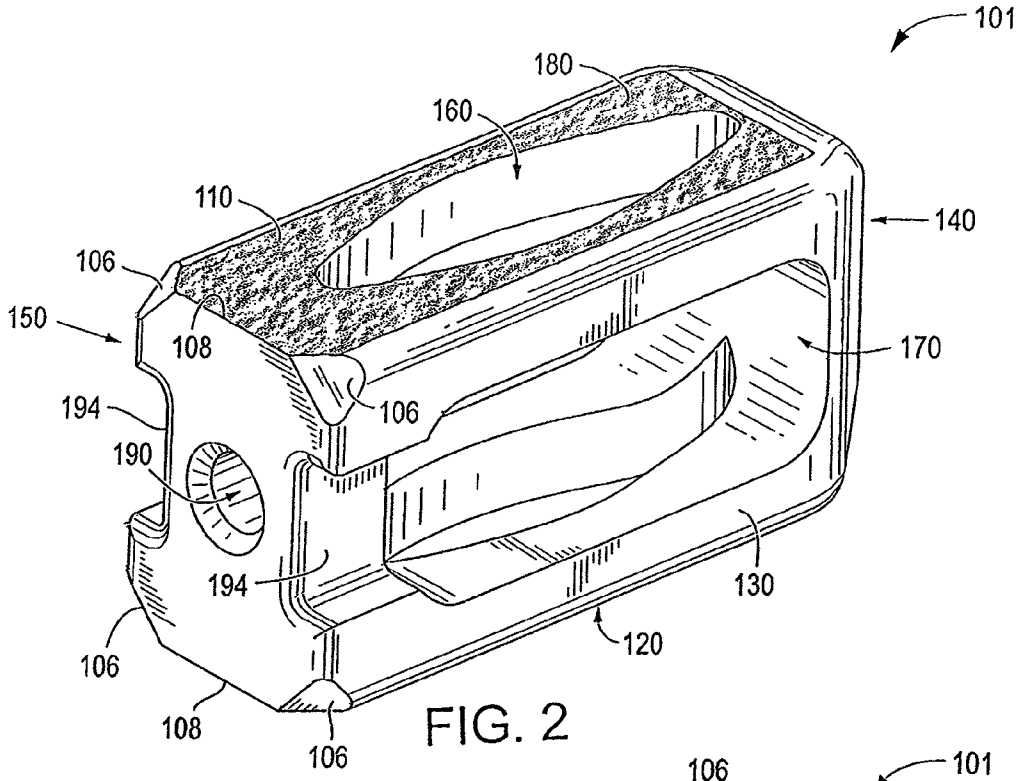
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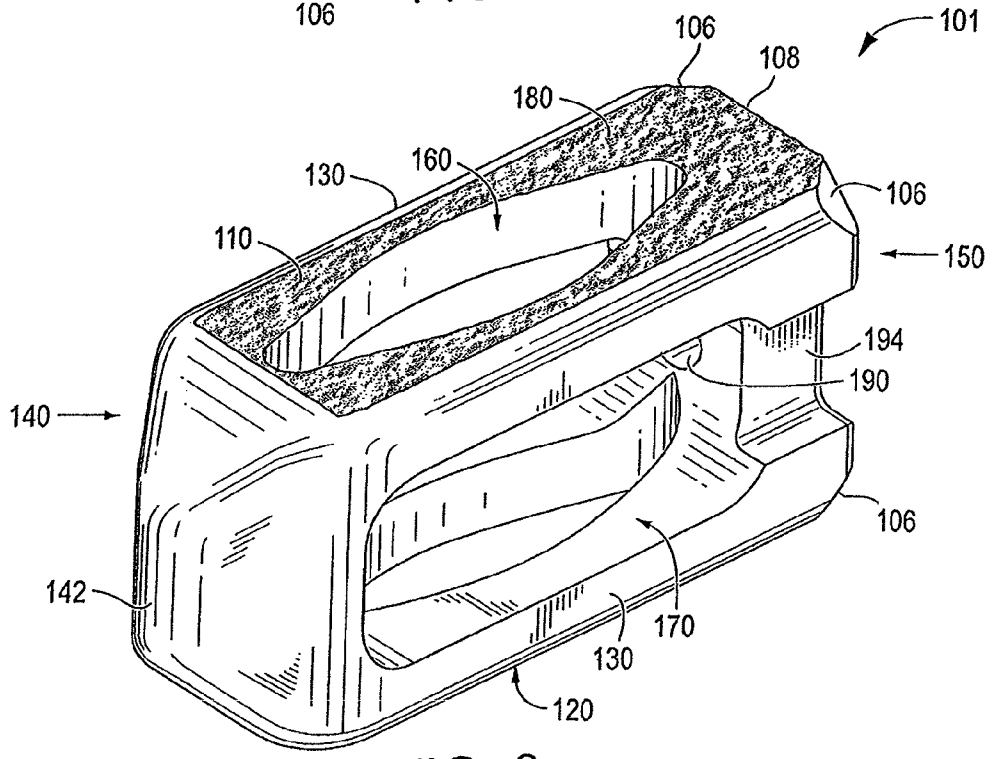
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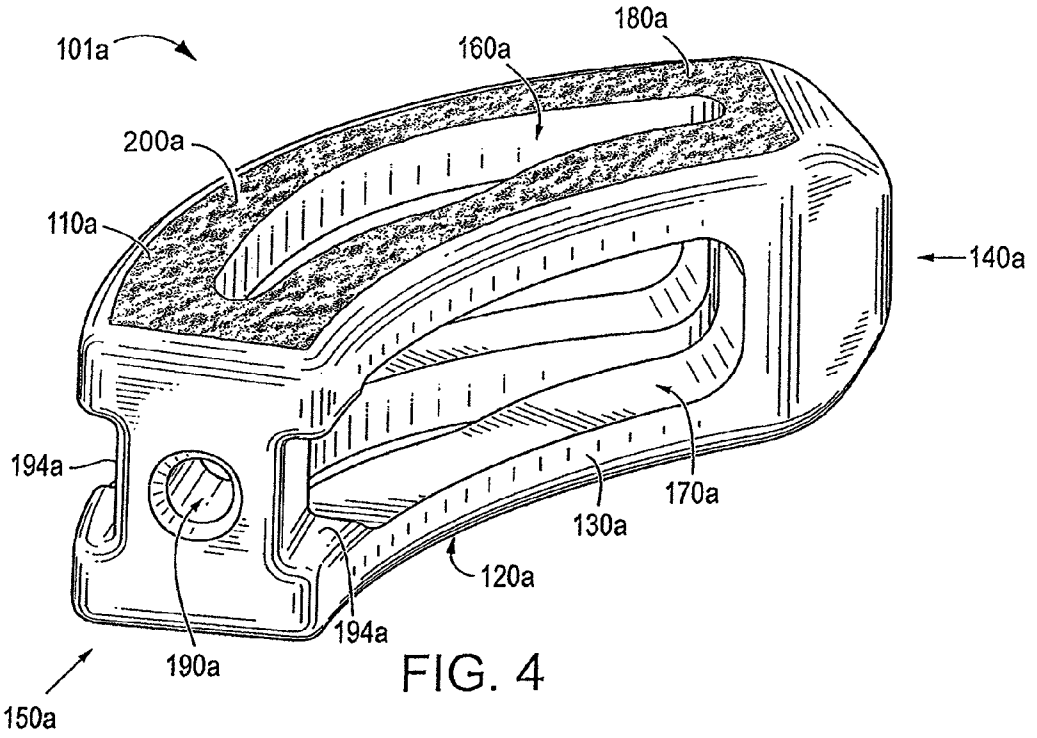
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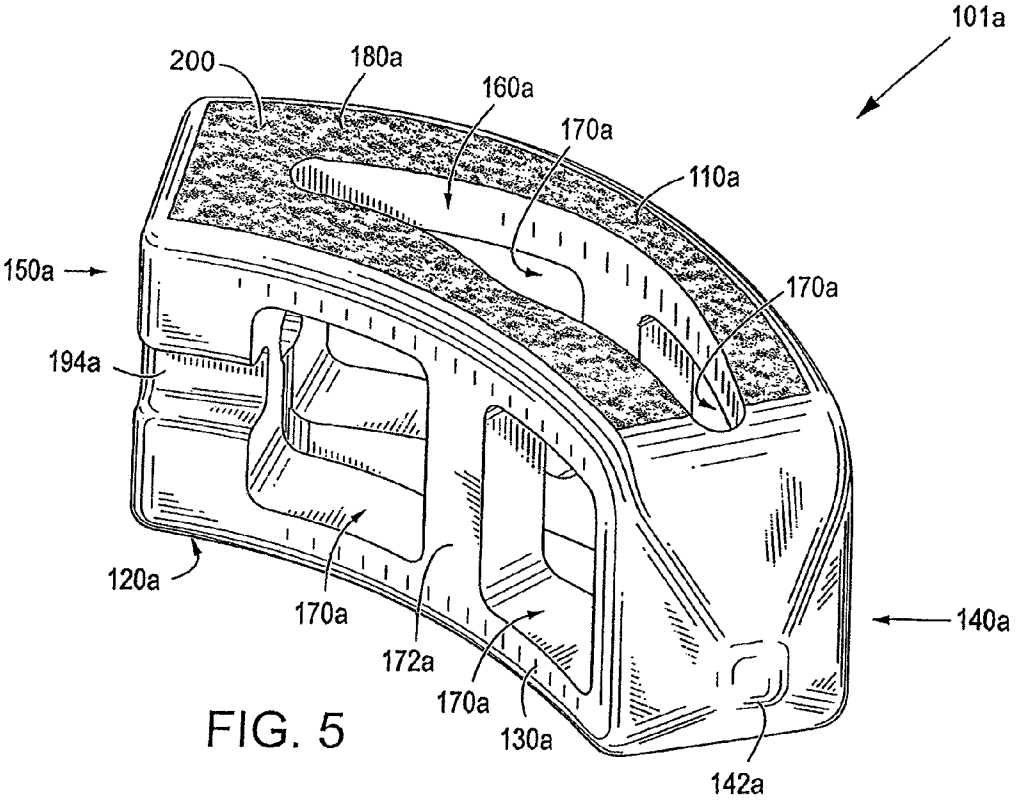
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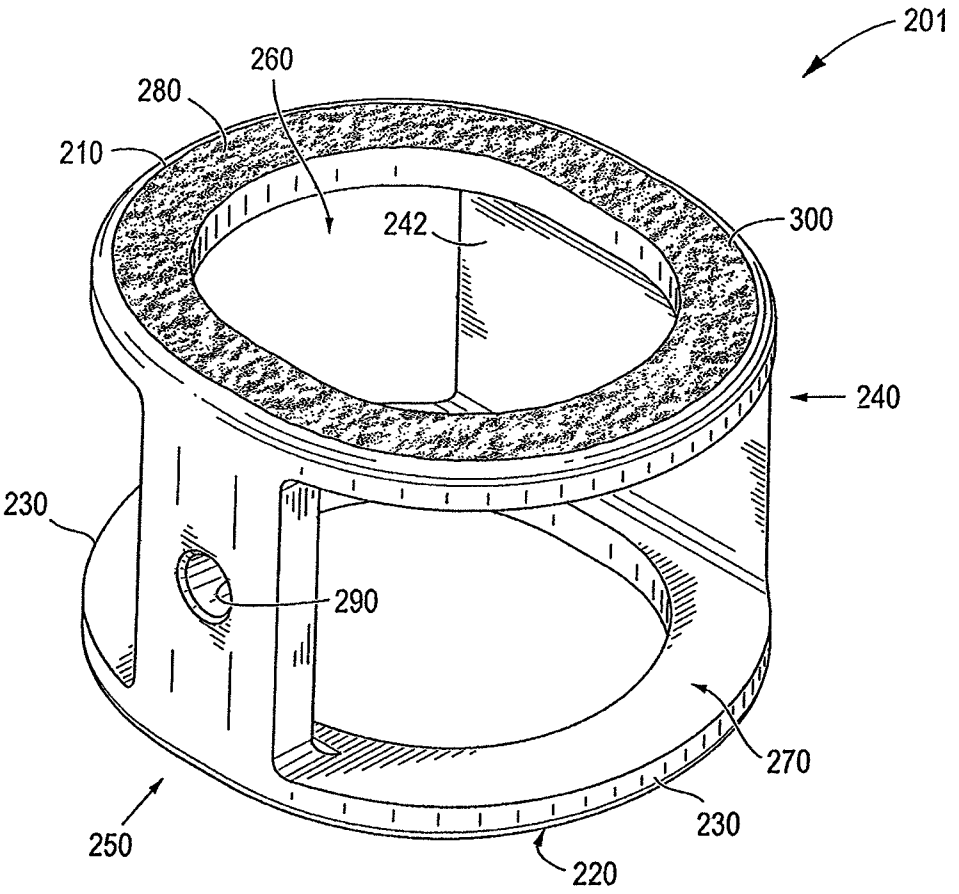
FIG. 5



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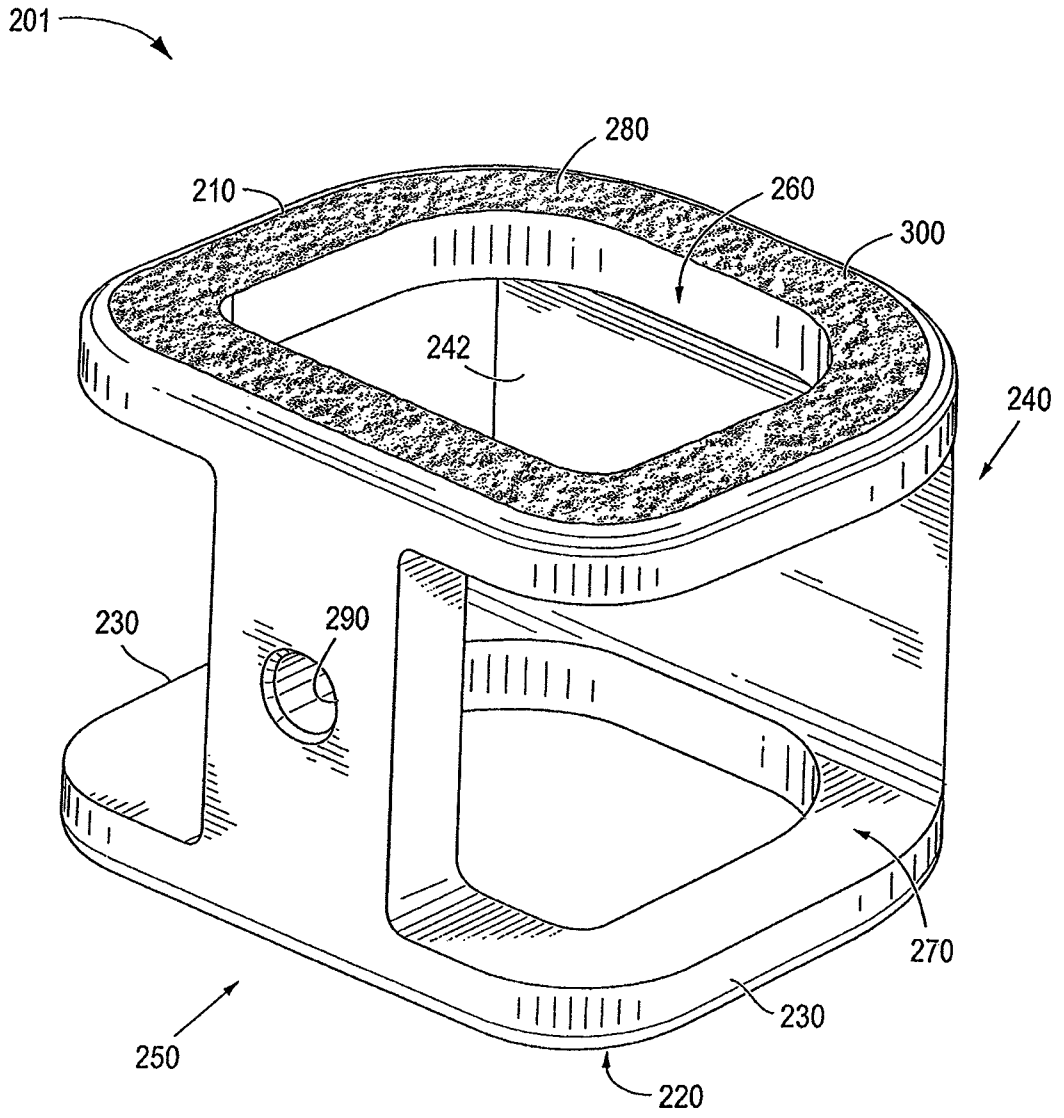


FIG. 7

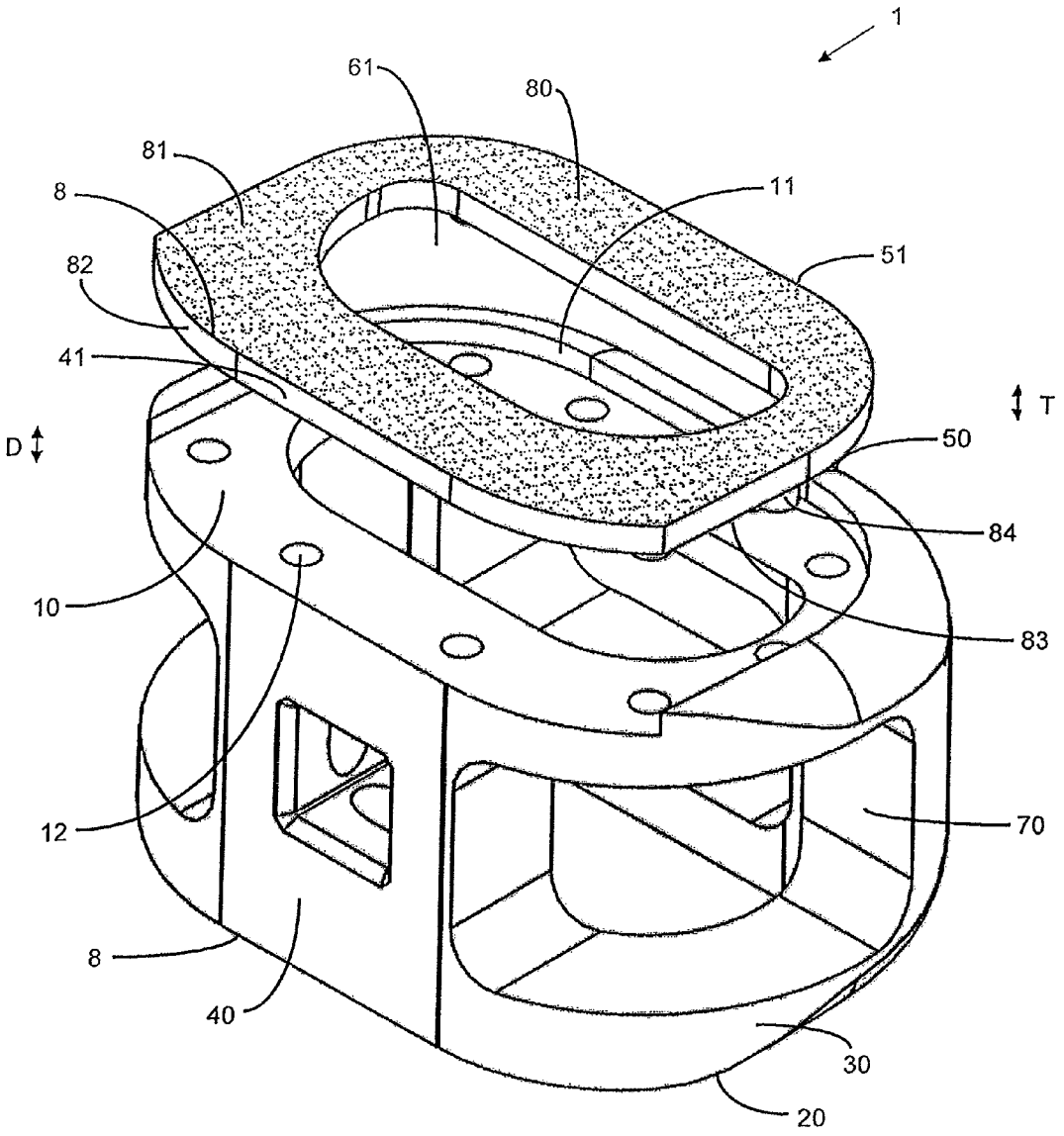


FIG. 8A

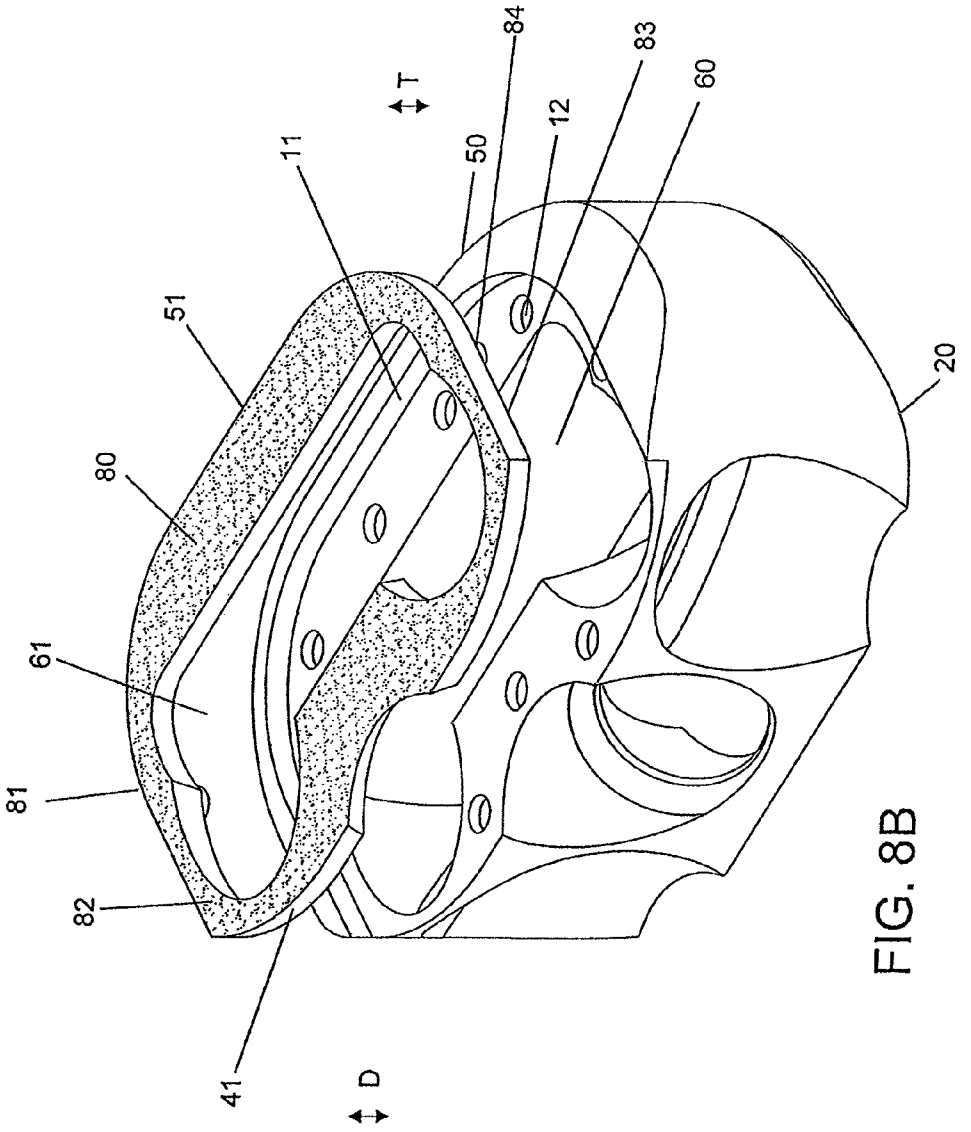
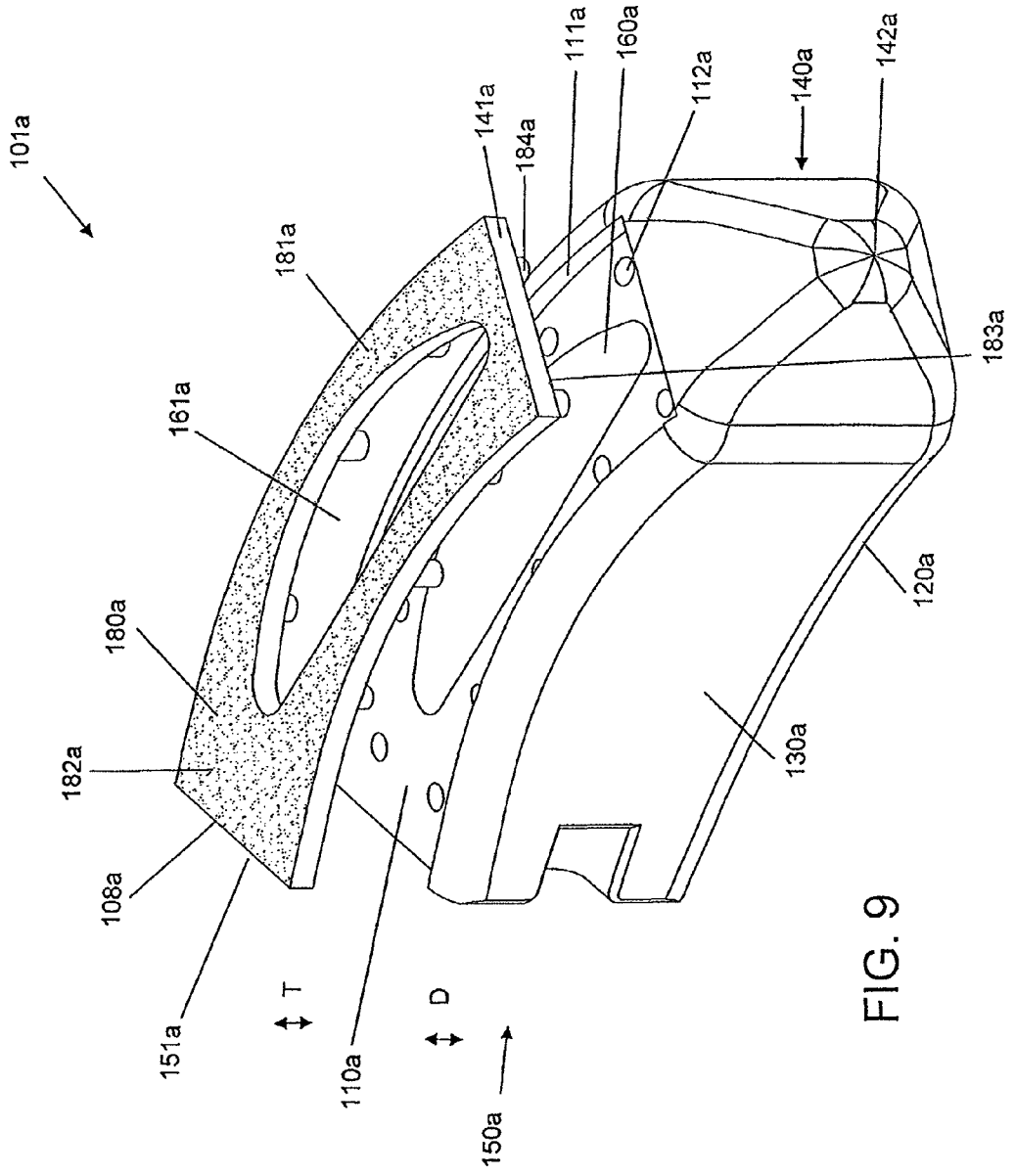


FIG. 8B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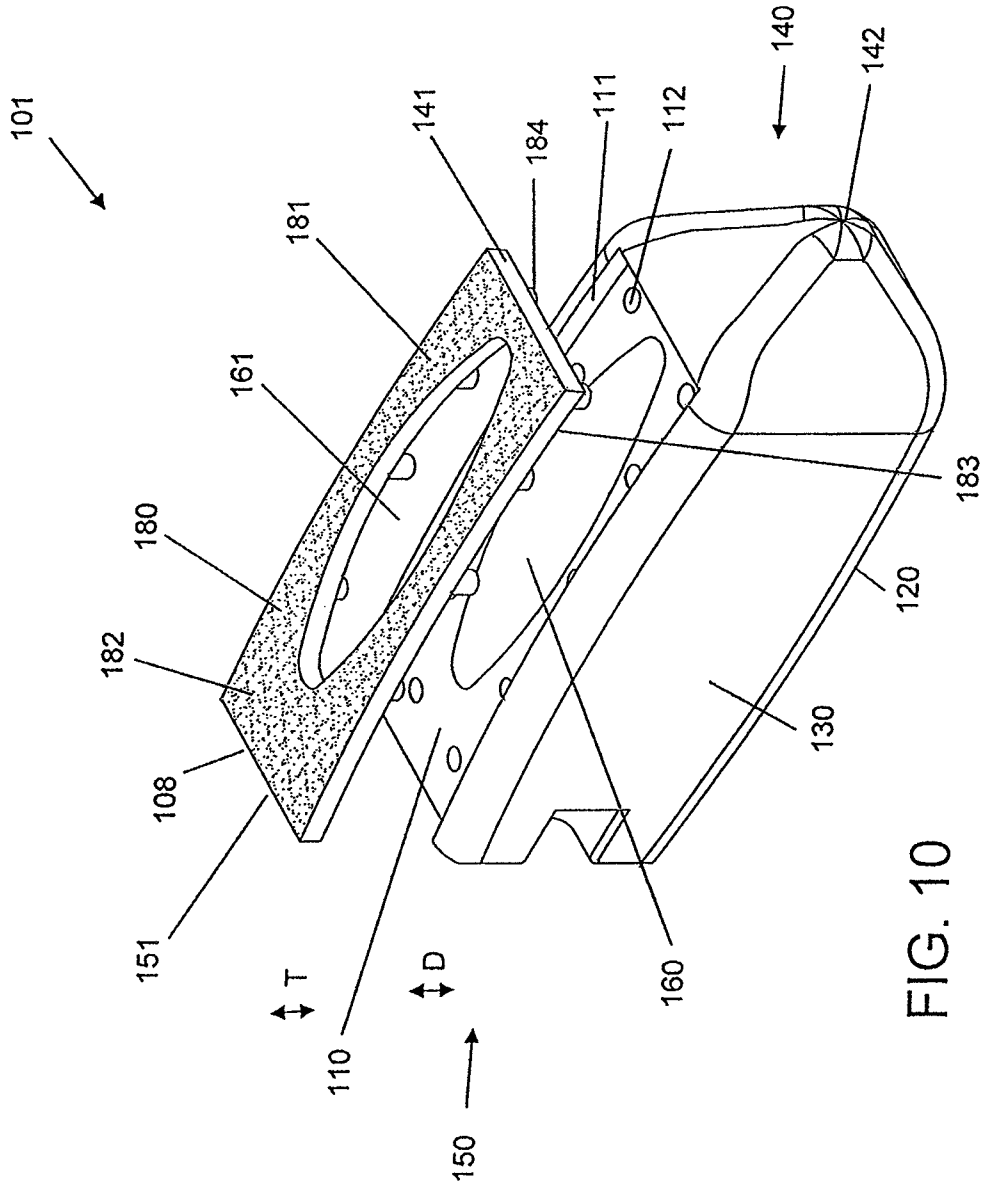
151a
T
110a
D
150a

FIG. 9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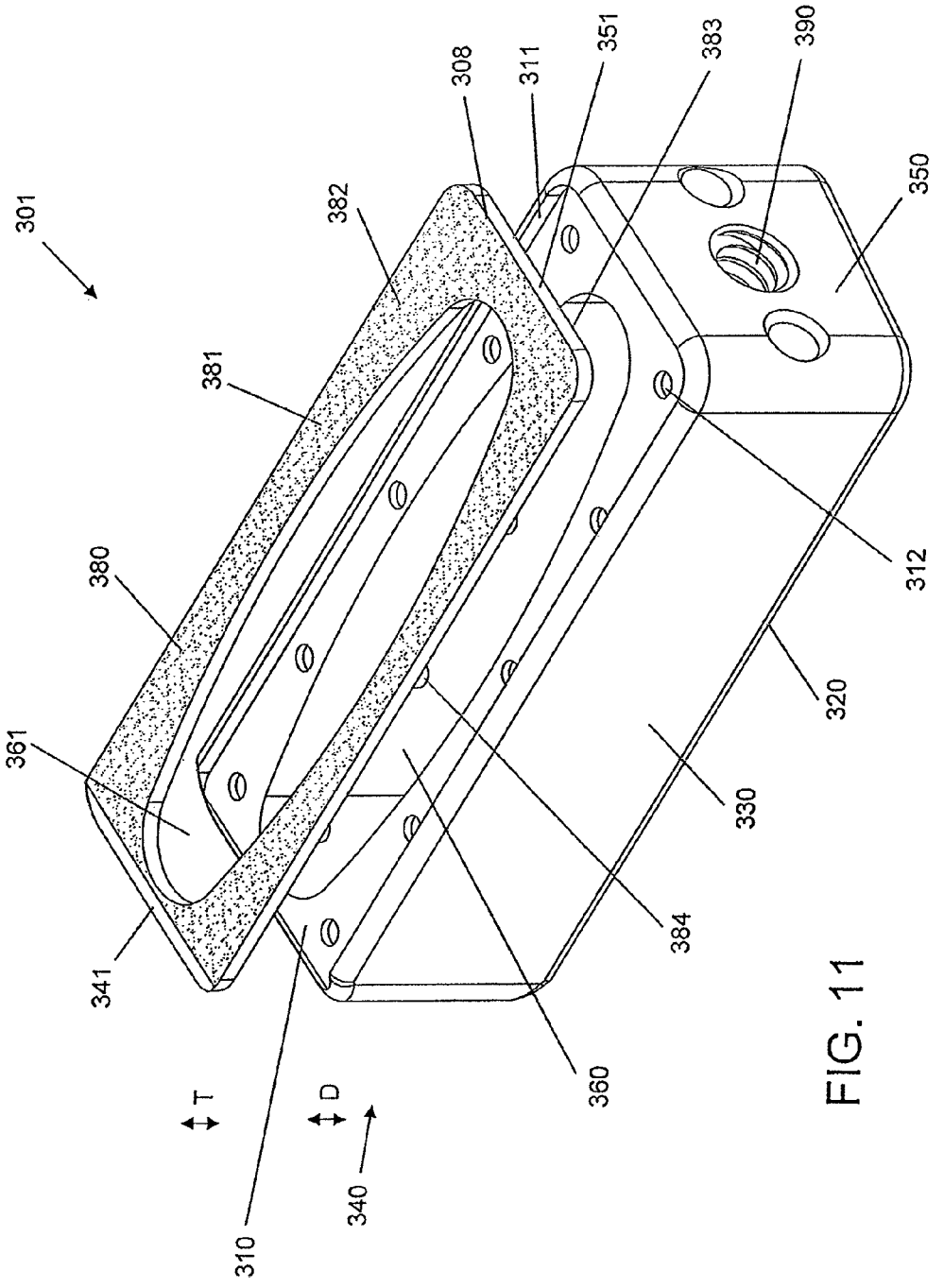
108
151
T
D
160
110
150

FIG. 10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T
D
340
310

FIG. 11

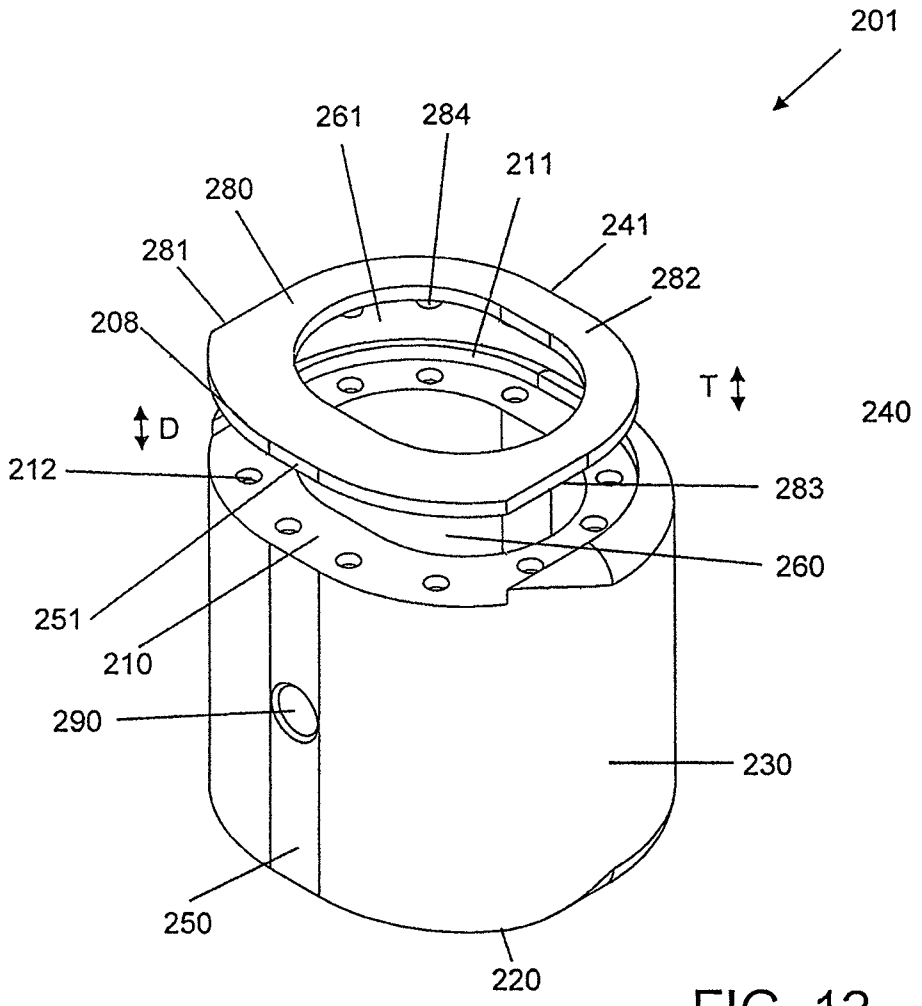
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FIG. 12

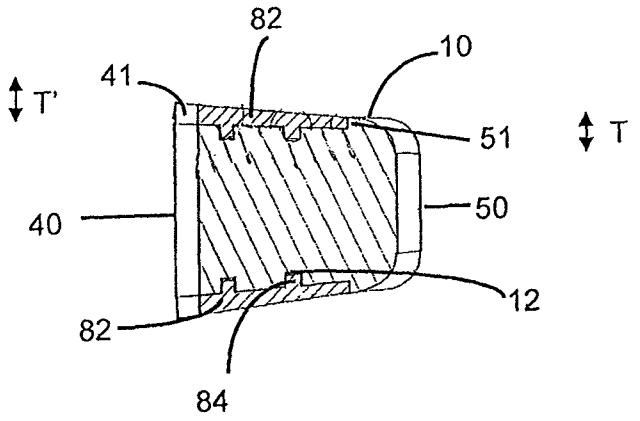


FIG. 13A

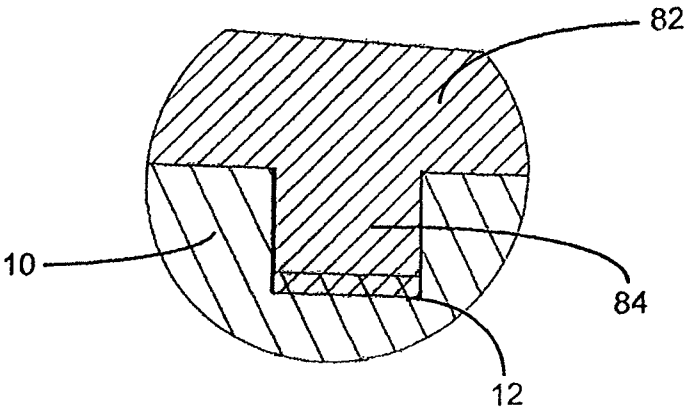


FIG. 13B

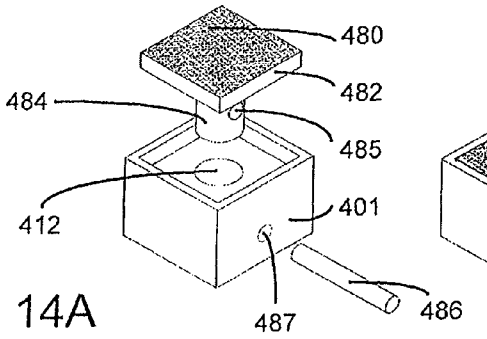


FIG. 14A

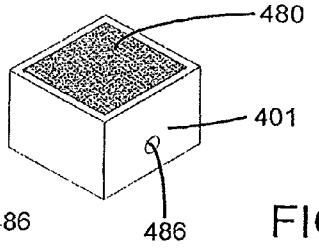


FIG. 14B

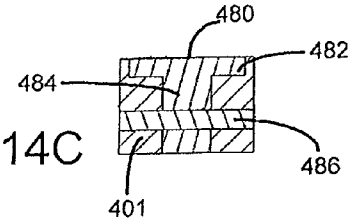


FIG. 14C

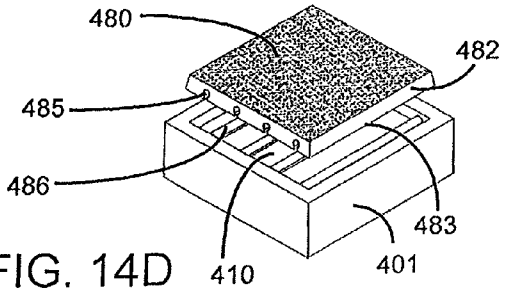


FIG. 14D

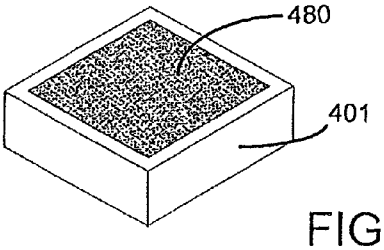


FIG. 14E

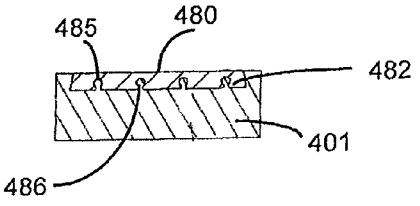


FIG. 14F

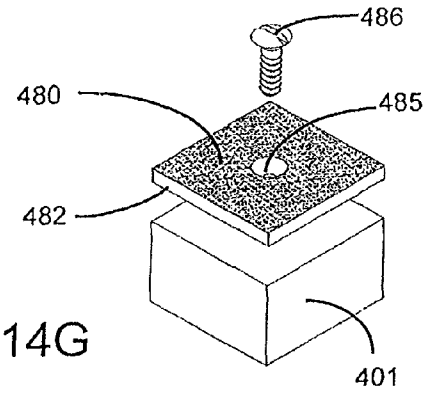


FIG. 14G

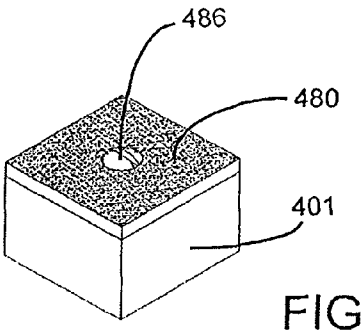


FIG. 14H

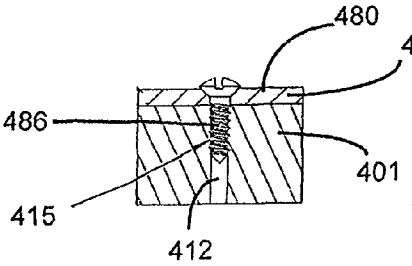


FIG. 14I

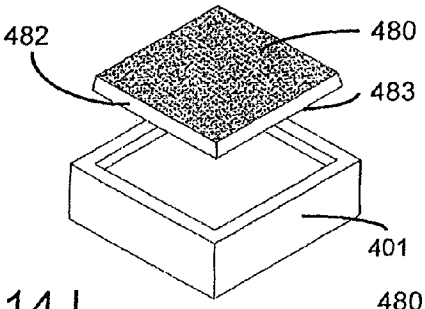


FIG. 14J

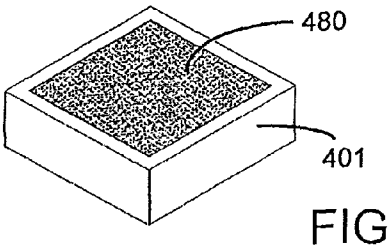


FIG. 14K

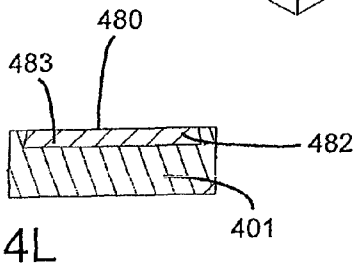
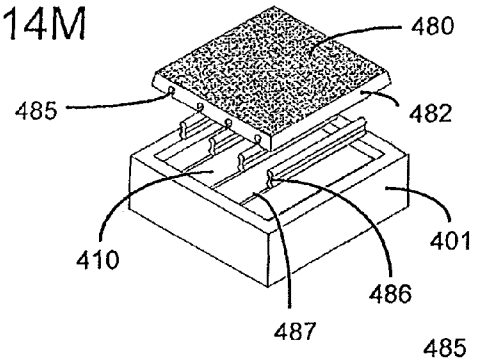


FIG. 14L

FIG. 14M



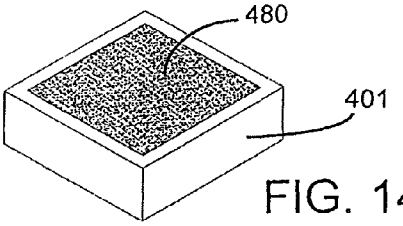


FIG. 14N

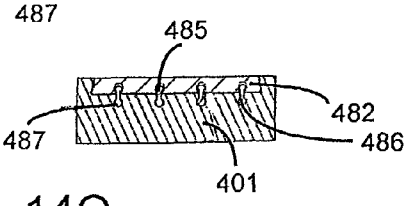


FIG. 14O

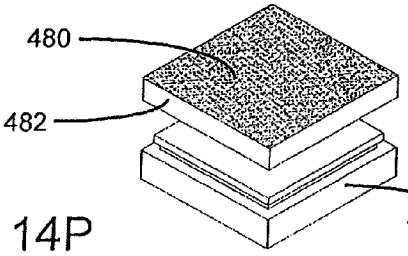


FIG. 14P

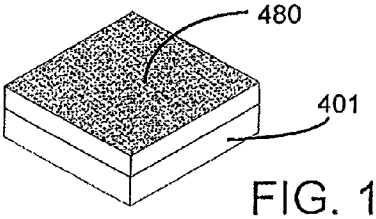


FIG. 14Q

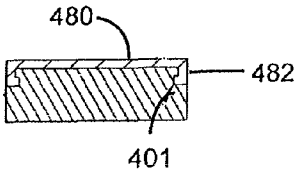


FIG. 14R

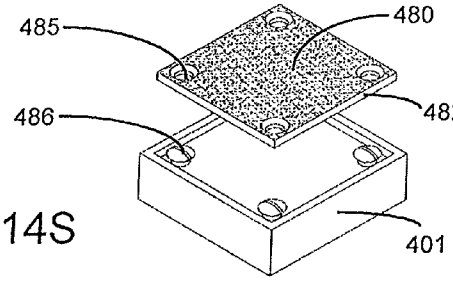


FIG. 14S

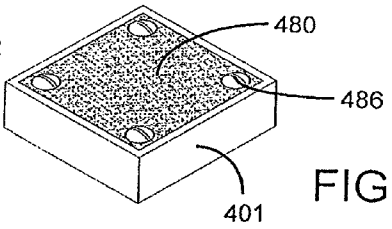


FIG. 14T

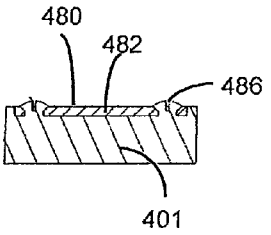


FIG. 14U

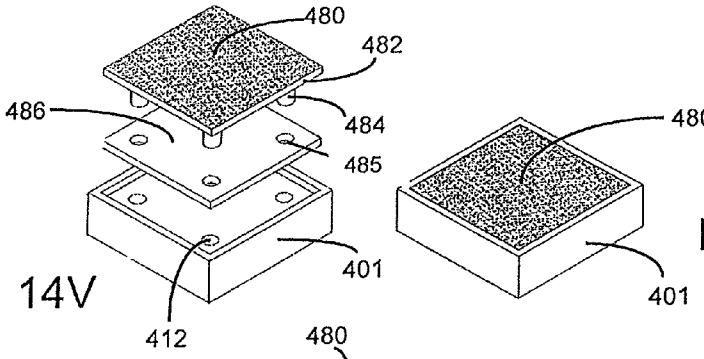


FIG. 14V

FIG. 14W

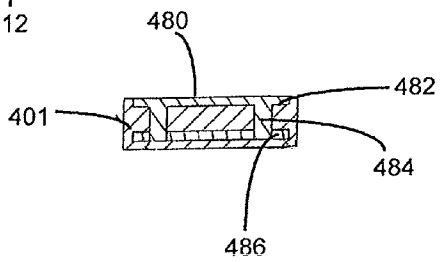


FIG. 14X

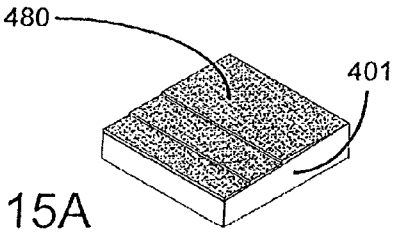


FIG. 15A

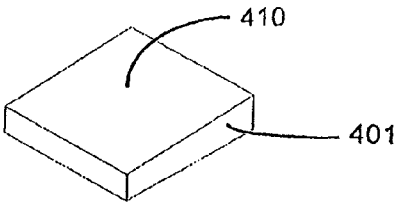


FIG. 15B

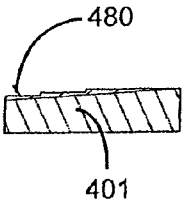


FIG. 15C

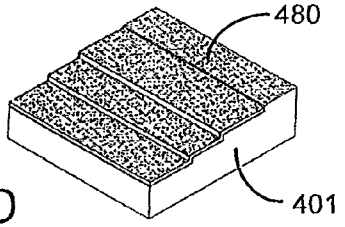


FIG. 15D

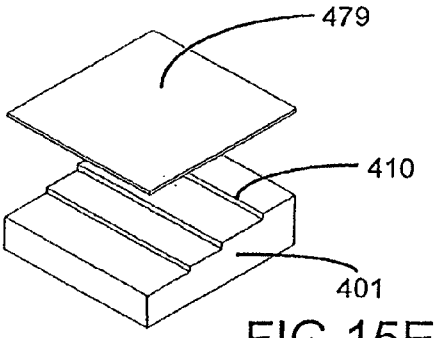
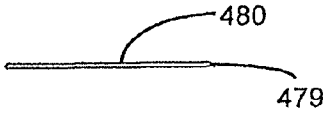


FIG 15E



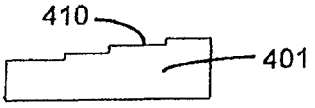


FIG. 15F

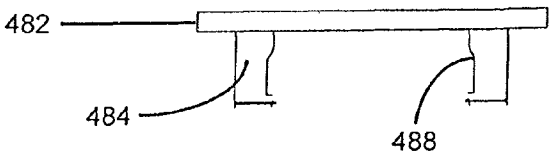


FIG. 16A

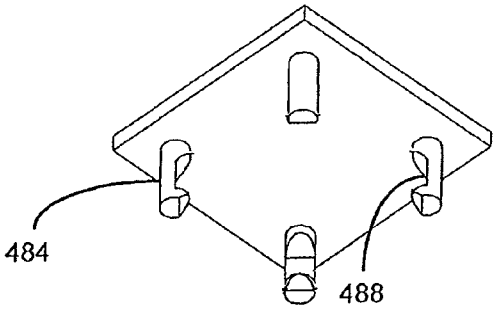


FIG. 16B

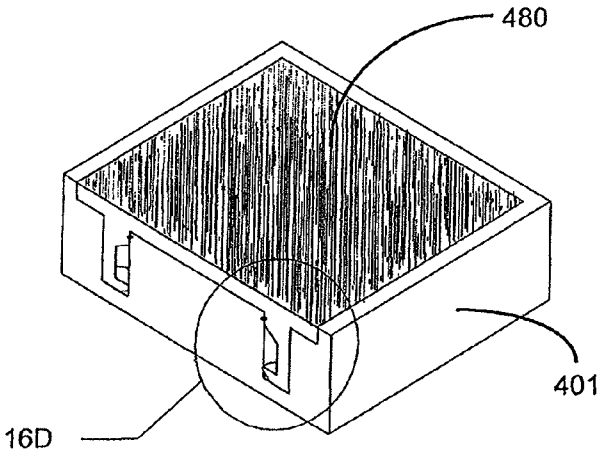


FIG. 16C

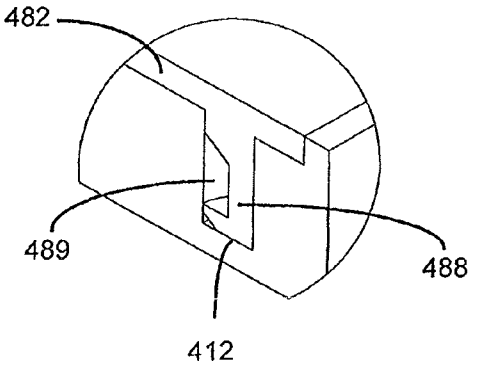


FIG. 16D

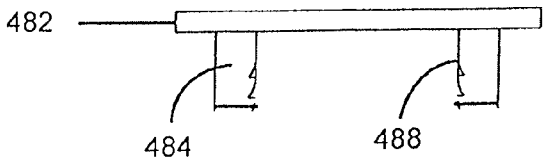


FIG. 16E

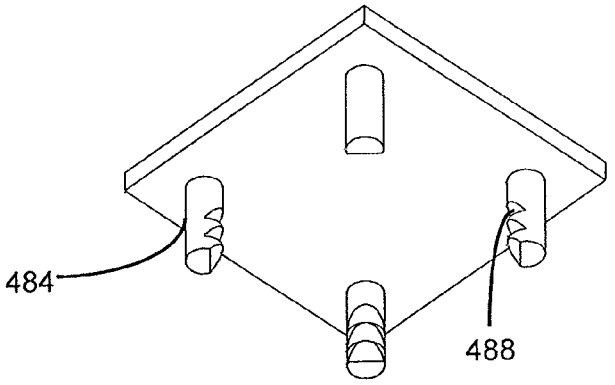


FIG. 16F

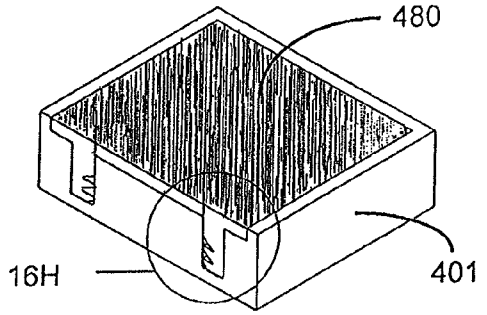


FIG. 16G

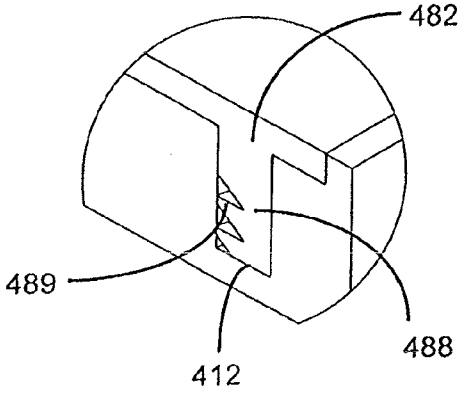


FIG. 16H

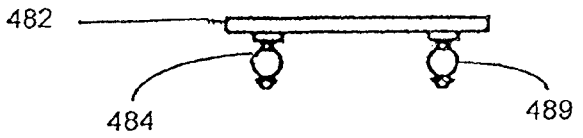


FIG. 16I

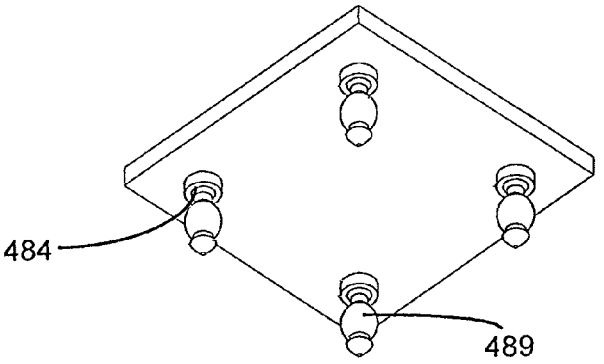


FIG. 16J

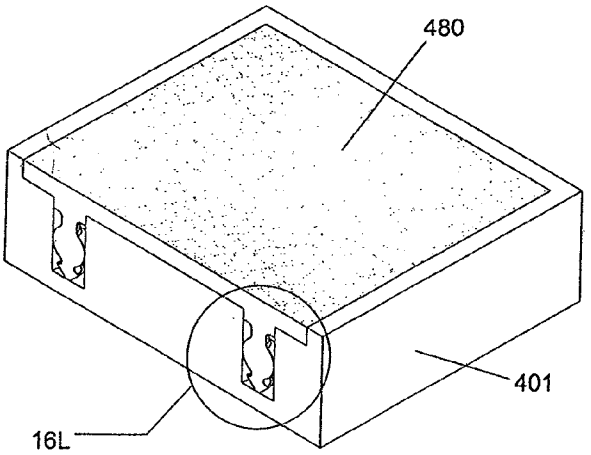


FIG. 16K

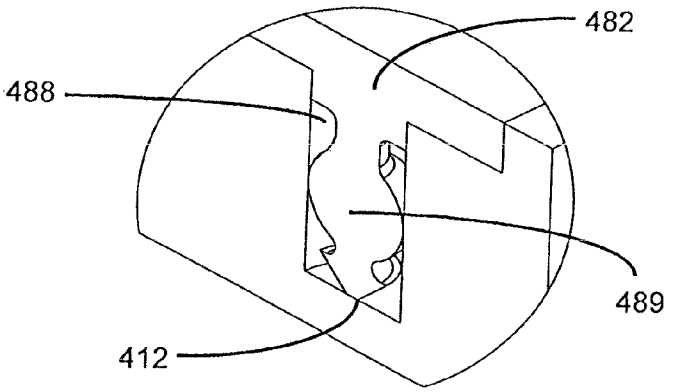


FIG. 16L

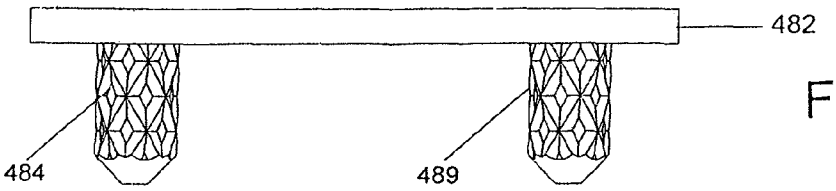


FIG. 16M

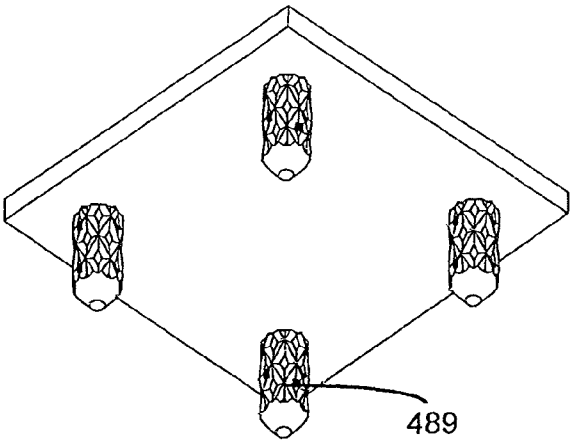


FIG. 16N

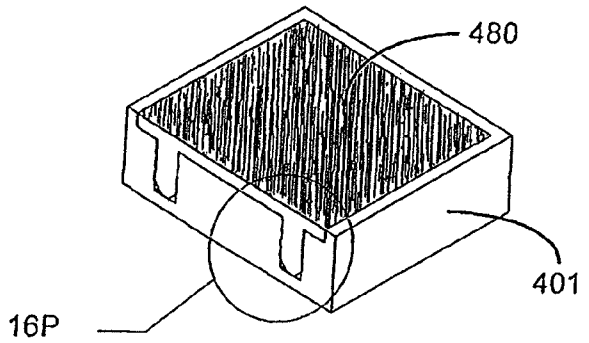


FIG. 16O

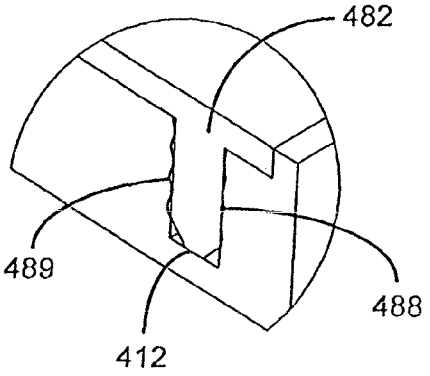


FIG. 16P

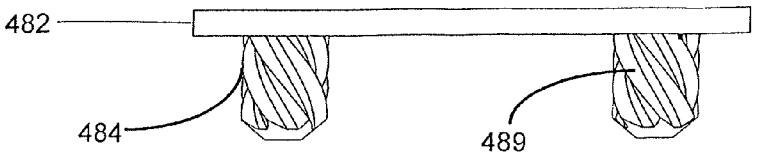


FIG. 16Q

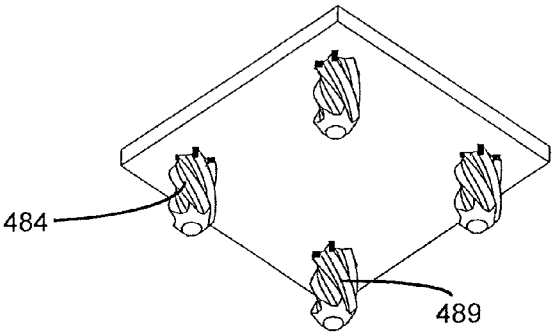


FIG. 16R

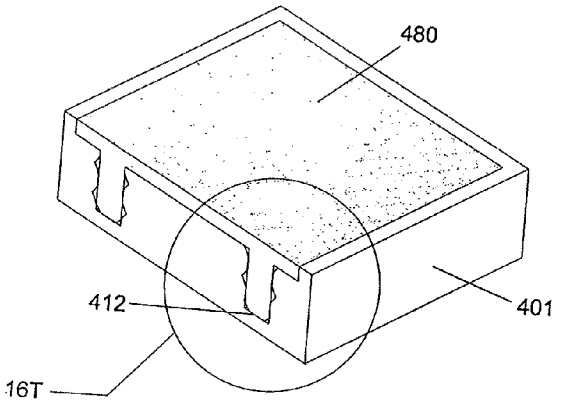


FIG. 16S

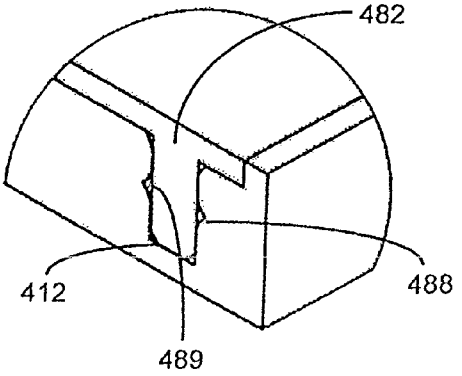


FIG. 16T

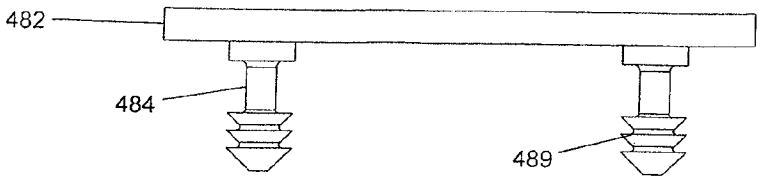


FIG. 16U

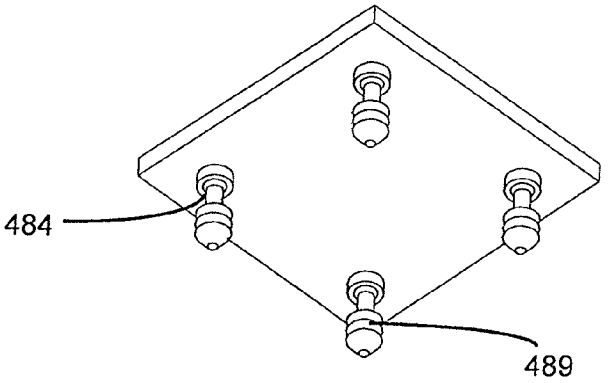


FIG. 16V

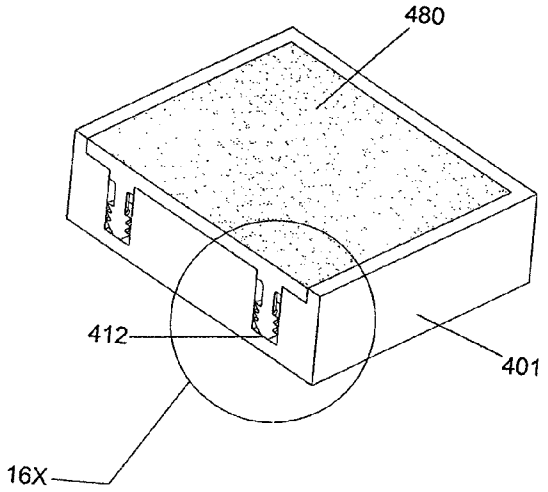


FIG. 16W

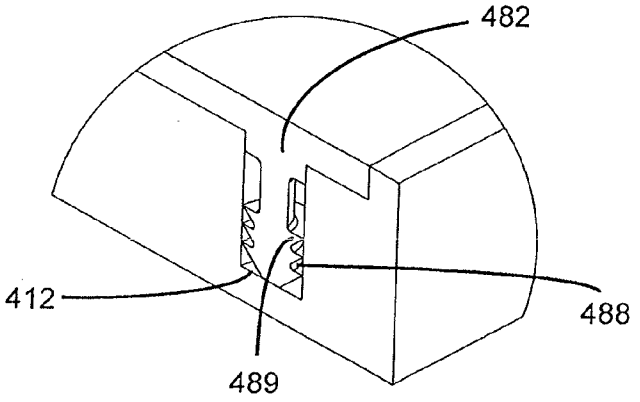


FIG. 16X

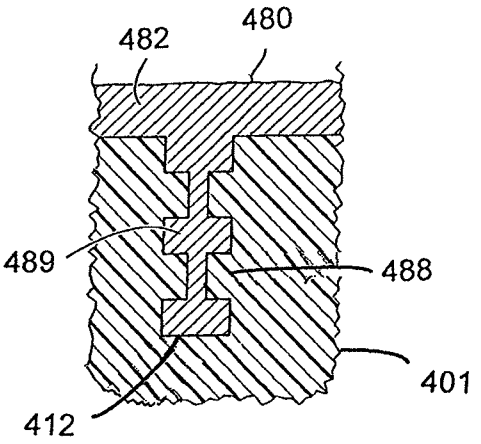


FIG.16Y

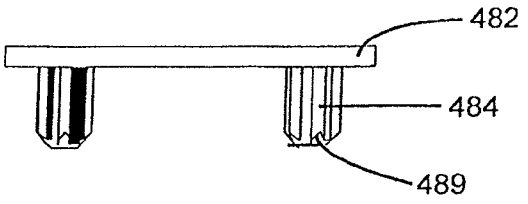


FIG. 17A

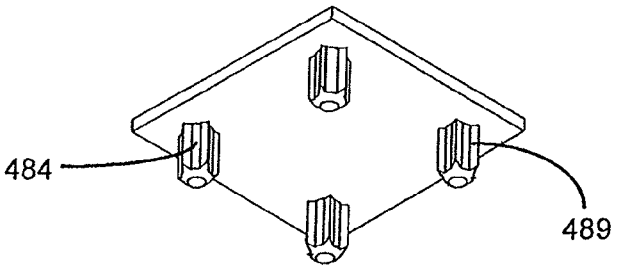


FIG. 17B

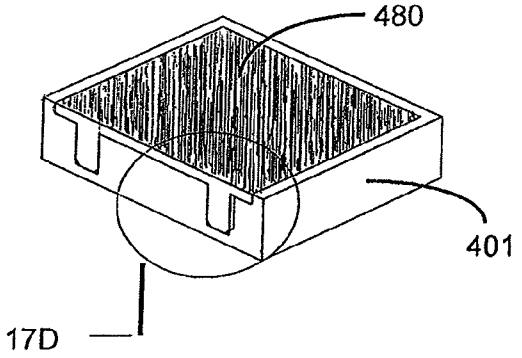


FIG. 17C

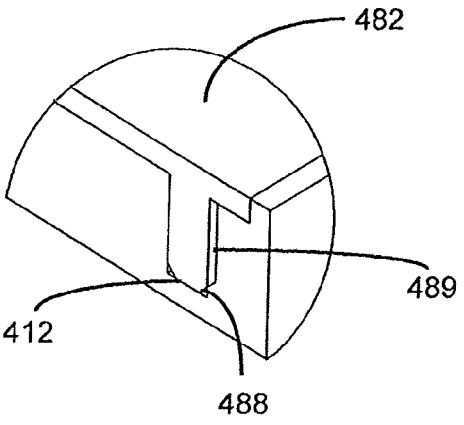


FIG. 17D

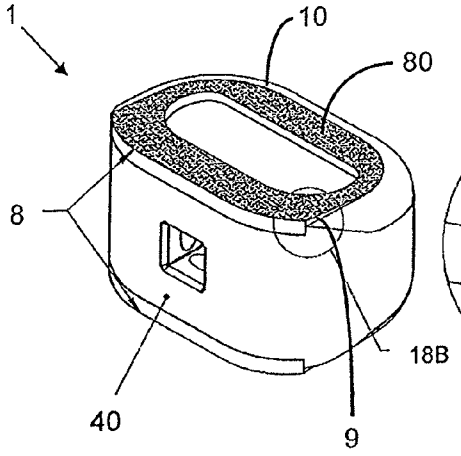


FIG. 18A

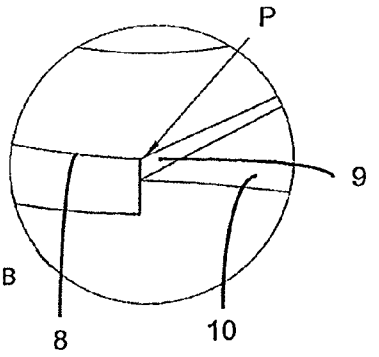


FIG. 18B

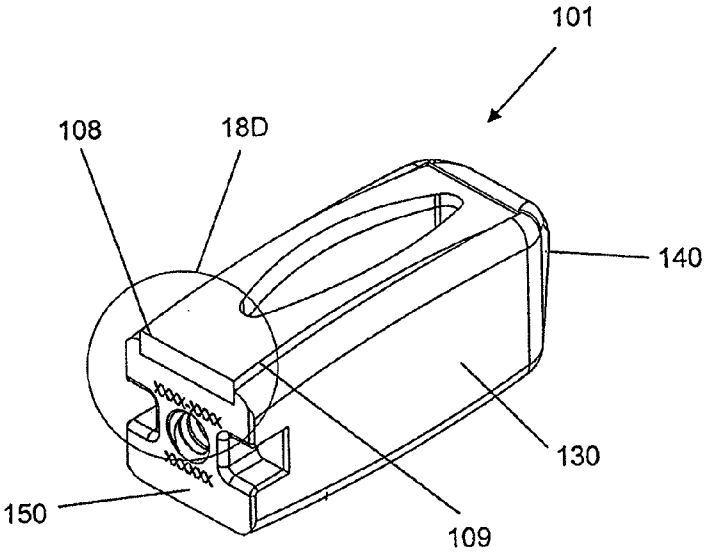


FIG. 18C

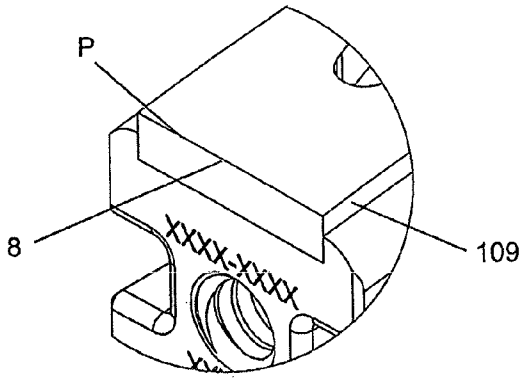


FIG. 18D

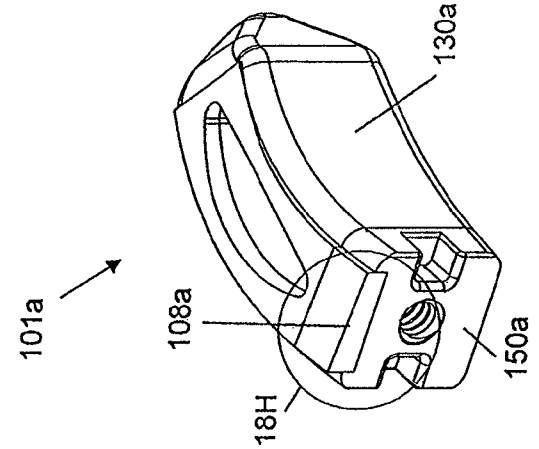


FIG. 18G

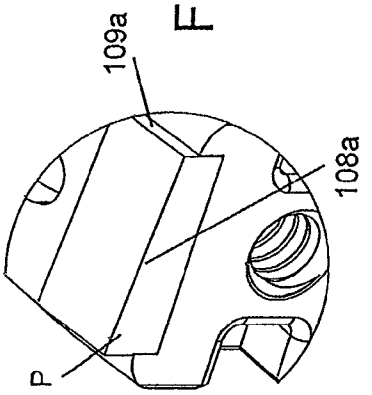


FIG. 18H

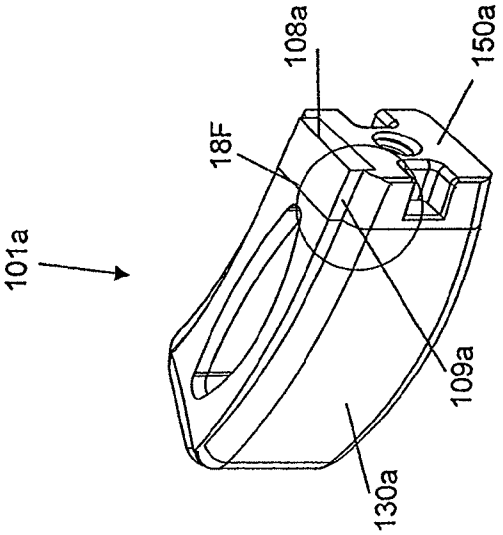


FIG. 18E

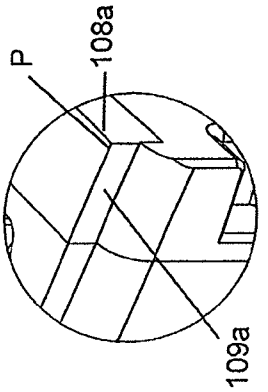
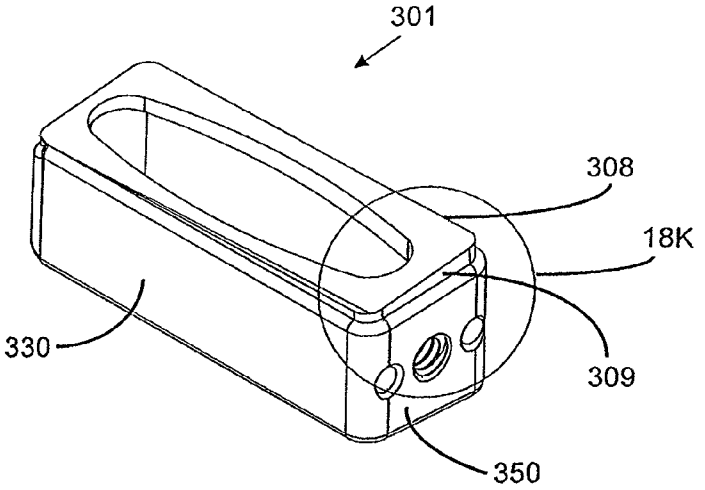


FIG. 18F

FIG. 18I



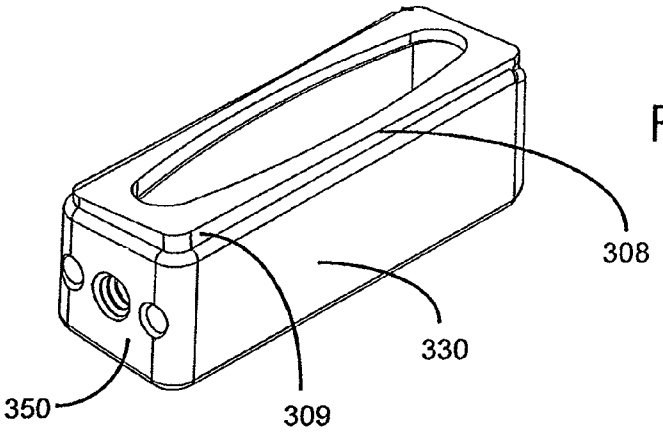
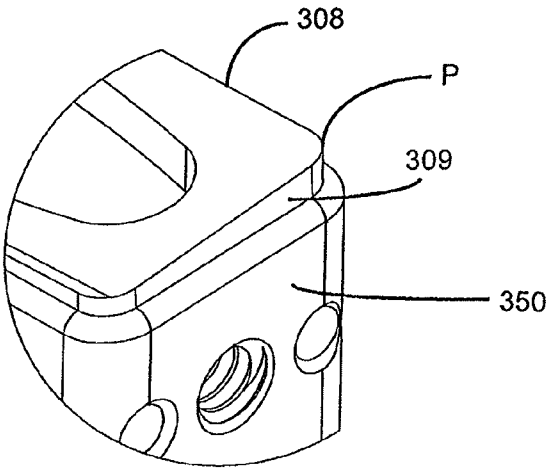


FIG. 18J

FIG. 18K



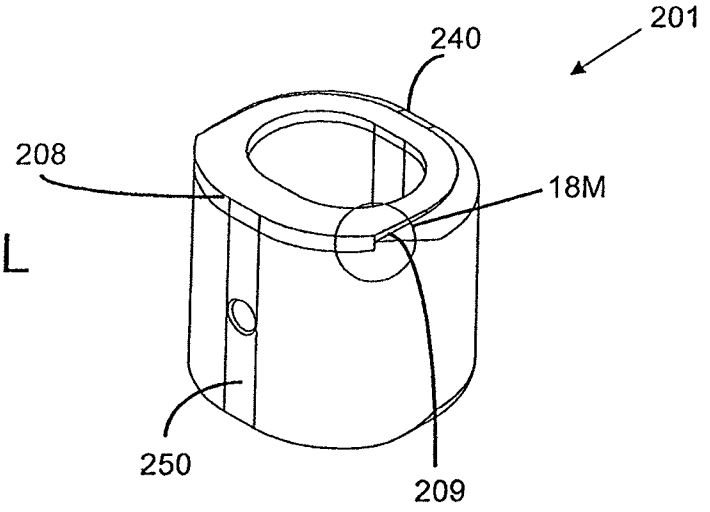


FIG. 18L

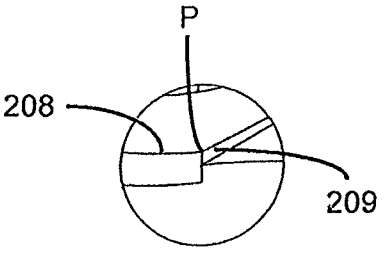


FIG. 18M

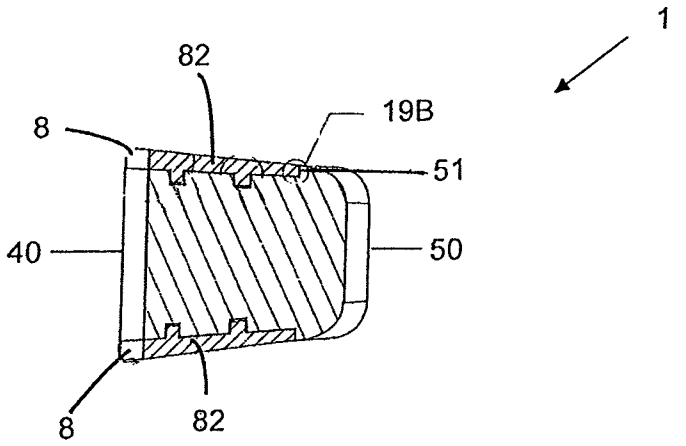


FIG. 19A

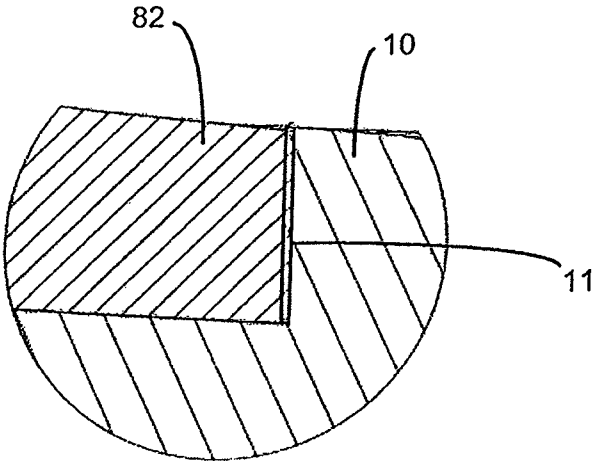


FIG. 19B

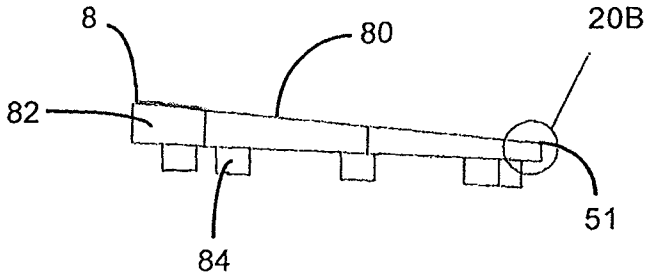
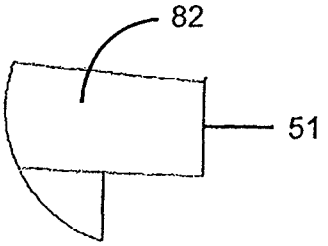


FIG. 20A

FIG. 20B



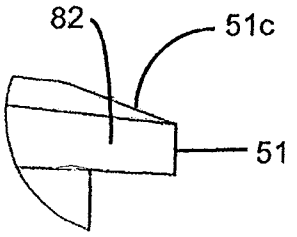


FIG. 20C

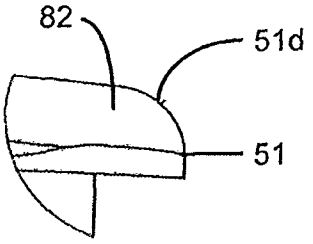


FIG. 20D

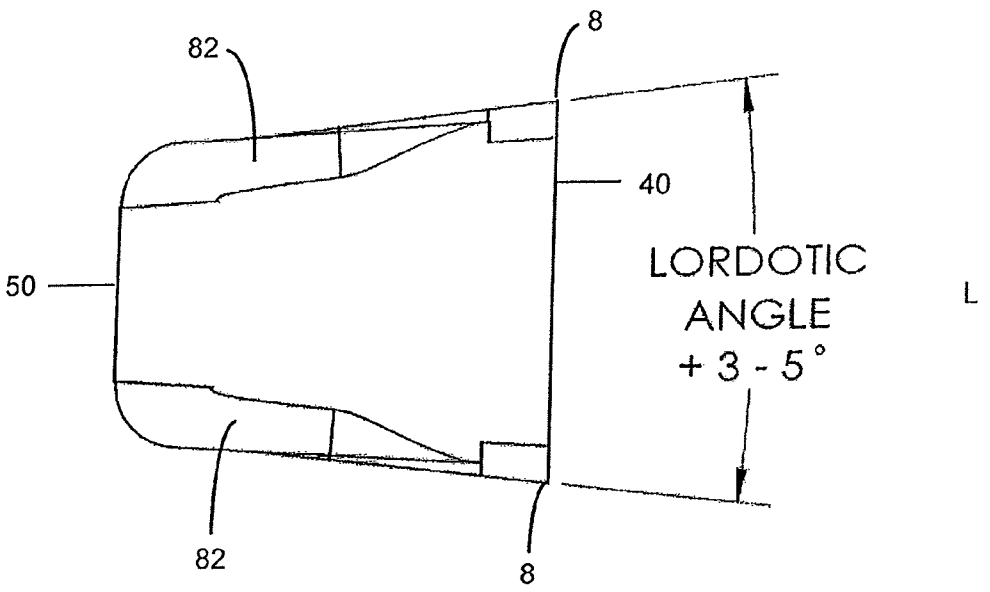


FIG. 21

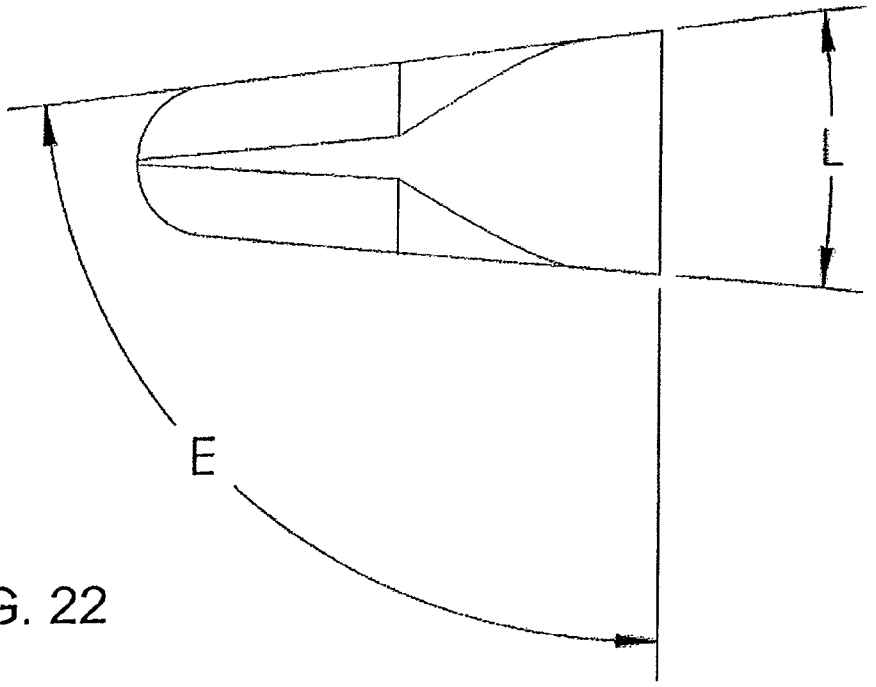


FIG. 22

ENDPLATE-PRESERVING SPINAL IMPLANT WITH AN INTEGRATION PLATE HAVING A ROUGHENED SURFACE TOPOGRAPHY

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 12/151,198, filed on May 5, 2008, and pending, which is a continuation-in-part of U.S. patent application Ser. No. 11/123,359, filed on May 6, 2005, and issued as U.S. Pat. No. 7,662,186. The contents of both prior applications are incorporated by reference in this document, in their entirety and for all purposes.

FIELD OF THE INVENTION

The invention relates generally to interbody spinal implants and methods of using such implants and, more particularly, to an implant including an integration plate affixed to the implant body and having a roughened surface topography.

BACKGROUND OF THE INVENTION

In the simplest terms, the spine is a column made of vertebrae and discs. The vertebrae provide the support and structure of the spine while the spinal discs, located between the vertebrae, act as cushions or "shock absorbers." These discs also contribute to the flexibility and motion of the spinal column. Over time, the discs may become diseased or infected, may develop deformities such as tears or cracks, or may simply lose structural integrity (e.g., the discs may bulge or flatten). Impaired discs can affect the anatomical functions of the vertebrae, due to the resultant lack of proper biomechanical support, and are often associated with chronic back pain.

Several surgical techniques have been developed to address spinal defects, such as disc degeneration and deformity. Spinal fusion has become a recognized surgical procedure for mitigating back pain by restoring biomechanical and anatomical integrity to the spine. Spinal fusion techniques involve the removal, or partial removal, of at least one intervertebral disc and preparation of the disc space for receiving an implant by shaping the exposed vertebral endplates. An implant is then inserted between the opposing endplates.

Several interbody implant systems have been introduced to facilitate interbody fusion. Traditional threaded implants involve at least two cylindrical bodies, each typically packed with bone graft material, surgically placed on opposite sides of the mid-sagittal plane through pre-tapped holes within the intervertebral disc space. This location is not the preferable seating position for an implant system, however, because only a relatively small portion of the vertebral endplate is contacted by these cylindrical implants. Accordingly, these implant bodies will likely contact the softer cancellous bone rather than the stronger cortical bone, or apophyseal rim, of the vertebral endplate. The seating of these threaded cylindrical implants may also compromise biomechanical integrity by reducing the area in which to distribute mechanical forces, thus increasing the apparent stress experienced by both the implant and vertebrae. Still further, a substantial risk of implant subsidence (defined as sinking or settling) into the softer cancellous bone of the vertebral body may arise from such improper seating.

In contrast, open ring-shaped cage implant systems are generally shaped to mimic the anatomical contour of the vertebral body. Traditional ring-shaped cages are generally comprised of allograft bone material, however, harvested from the human femur. Such allograft bone material restricts the usable size and shape of the resultant implant. For example, many of these femoral ring-shaped cages generally have a medial-lateral width of less than 25 mm. Therefore, these cages may not be of a sufficient size to contact the strong cortical bone, or apophyseal rim, of the vertebral endplate. These size-limited implant systems may also poorly accommodate related instrumentation such as drivers, reamers, distractors, and the like. For example, these implant systems may lack sufficient structural integrity to withstand repeated impact and may fracture during implantation. Still further, other traditional non-allograft ring-shaped cage systems may be size-limited due to varied and complex supplemental implant instrumentation which may obstruct the disc space while requiring greater exposure of the operating space. These supplemental implant instrumentation systems also generally increase the instrument load upon the surgeon.

The surgical procedure corresponding to an implant system should preserve as much vertebral endplate bone surface as possible by minimizing the amount of bone removed. This vertebral endplate bone surface, or subchondral bone, is generally much stronger than the underlying cancellous bone. Preservation of the endplate bone stock ensures biomechanical integrity of the endplates and minimizes the risk of implant subsidence. Thus, proper interbody implant design should provide for optimal seating of the implant while utilizing the maximum amount of available supporting vertebral bone stock.

Nevertheless, traditional implantation practices often do not preserve critical bone structures such as vertebral endplates during the surgical procedure. In some cases, the implant devices themselves necessitate removal of bone and were not designed or implanted with the intent to preserve critical bone structures during or after implantation.

In summary, at least ten, separate challenges can be identified as inherent in traditional anterior spinal fusion devices. Such challenges include: (1) end-plate preparation; (2) implant difficulty; (3) materials of construction; (4) implant expulsion; (5) implant subsidence; (6) insufficient room for bone graft; (7) stress shielding; (8) lack of implant incorporation with vertebral bone; (9) limitations on radiographic visualization; and (10) cost of manufacture and inventory.

SUMMARY OF THE INVENTION

The invention is directed to interbody spinal implants and to methods of using such implants. The implants can be inserted, using methods of the invention, from a variety of vantages, including anterior, antero-lateral, and lateral implantation. The spinal implant is preferably adapted to be inserted into a prepared disc space via a procedure which does not destroy the vertebral end-plates, or contacts the vertebral end-plates only peripherally, allowing the intact vertebral end-plates to deflect like a diaphragm under axial compressive loads generated due to physiologic activities and pressurize the bone graft material disposed inside the spinal implant.

An implant preferably comprises a body and at least one integration plate, which are joined together. The body preferably comprises a top surface, a bottom surface, opposing lateral sides, opposing anterior and posterior portions, a substantially hollow center, and a single vertical aperture extending from the top surface to the bottom surface. The vertical aperture has a size and shape for maximizing the surface area of the top surface and the bottom surface available proximate

the anterior and posterior portions while maximizing both radiographic visualization and access to the substantially hollow center, defines a transverse rim with a varying width or thickness, and has a maximum width at its center between the opposing lateral sides. The anterior portion of the body or the posterior portion of the body may comprise an opening for engaging a delivery device, facilitating delivery of bone graft material to the substantially hollow center, enhancing visibility of the implant, or providing access to bone graft material.

At least a portion of the top surface of the body is recessed and comprises a plurality of holes in the recessed portion. In some embodiments, at least a portion of the bottom surface of the body is recessed and comprises a plurality of holes in the recessed portion. The recessed portion of the top surface and/or the recessed portion of the bottom surface are preferably recessed to a depth corresponding to the thickness of the integration plate.

The integration plate comprises a top surface, a bottom surface, opposing lateral sides, opposing anterior and posterior portions, and a single vertical aperture extending from the top surface to the bottom surface. Preferably, the vertical aperture aligns with the single vertical aperture of the body, defines a transverse rim with a varying width or thickness, and has a maximum width at its center. The top surface of the integration plate comprises a roughened surface topography adapted to grip bone and inhibit migration of the implant. The bottom surface of the integration plate comprises a plurality of posts positioned to align with the plurality of holes and affix the integration plate to the body. The implant may comprise an integration plate on the top surface and the bottom surface of the body.

The substantially hollow portion of the body may contain a bone graft material adapted to facilitate the formation of a solid fusion column within the spine. The bone graft material may be cancellous autograft bone, allograft bone, demineralized bone matrix (DBM), porous synthetic bone graft substitute, bone morphogenic protein (BMP), or a combination thereof. The body may comprise a wall closing at least one of the opposing anterior and posterior portions of the body for containing the bone graft material.

The implant body and/or the integration plate may be fabricated from a metal. A preferred metal is titanium. The implant body may be fabricated from a non-metallic material, non-limiting examples of which include polyetherether-ketone, hedrocel, ultra-high molecular weight polyethylene, and combinations thereof. The implant body may be fabricated from both a metal and a non-metallic material, including a composite thereof. For example, a composite may be formed, in part, of titanium and, in part, of polyetherether-ketone, hedrocel, ultra-high molecular weight polyethylene, or combinations thereof.

The body and the integration plate are preferably compatibly shaped, such that the implant with the body and integration plate joined together may have a generally oval shape, a generally rectangular shape, a generally curved shape, or any other shape described or exemplified in this specification. Thus, for example, the body and the integration plate may be generally oval-shaped in transverse cross-section. The body and the integration plate may be generally rectangular-shaped in transverse cross-section. The body and the integration plate may be generally curved-shaped in transverse cross-section.

The implant may comprise a lordotic angle adapted to facilitate alignment of the spine. At least one of the anterior and posterior portions of the integration plate may comprise an anti-expulsion edge to resist pullout of the implant from the spine of a patient into which the implant has been implanted.

The invention also features systems that include such interbody spinal implants. The systems may comprise an implant and a distractor. The systems may further comprise a rasp. The systems may further comprise an implant holder capable of engaging an opening on the anterior portion of the spinal implant. The systems may further comprise a bone graft material, non-limiting examples of which include cancellous autograft bone, allograft bone, demineralized bone matrix (DBM), porous synthetic bone graft substitute, bone morphogenic protein (BMP), or a combination thereof.

It is to be understood that both the foregoing general description and the following detailed description are exemplary, but are not restrictive, of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is best understood from the following detailed description when read in connection with the accompanying drawing. It is emphasized that, according to common practice, the various features of the drawing are not to scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawing are the following figures:

FIG. **1**A shows a perspective view of an embodiment of the interbody spinal implant having a generally oval shape and roughened surface topography on the top surface;

FIG. **1**B shows a top view of the first embodiment of the interbody spinal implant illustrated in FIG. **1**A;

FIG. **2** shows a perspective view from the front of another embodiment of the interbody spinal implant according to the invention;

FIG. **3** shows a perspective view from the rear of the embodiment of the interbody spinal implant illustrated in FIG. **2**;

FIG. **4** shows a perspective view from the front of yet another embodiment of the interbody spinal implant according to the invention;

FIG. **5** shows a perspective view from the rear of the embodiment of the interbody spinal implant illustrated in FIG. **4** highlighting an alternative transverse aperture;

FIG. **6** shows a perspective view of another embodiment of the interbody spinal implant having a generally oval shape and being especially well adapted for use in a cervical spine surgical procedure;

FIG. **7** shows a perspective view of an implant having a generally box shape;

FIG. **8**A shows an exploded view of a generally oval-shaped implant with an integration plate;

FIG. **8**B shows an exploded view of a generally oval-shaped implant with integration fixation and an integration plate;

FIG. **9** shows an exploded view of a curved implant with an integration plate;

FIG. **10** shows an exploded view of a posterior implant with an integration plate;

FIG. **11** shows an exploded view of a lateral lumbar implant with an integration plate;

FIG. **12** shows an exploded view of a generally oval-shaped anterior cervical implant with an integration plate;

FIG. **13**A shows a cut-away view of an integration plate;

FIG. **13**B shows a close-up of the cut-away portion illustrated in FIG. **13**A with the post of the integration plate fit within a hole in the implant top surface;

FIG. **14**A shows an exploded view of a pin connection suitable for mounting an integration plate onto an implant;

FIG. **14**B shows the pin connection illustrated in FIG. **14**A with the components assembled;

FIG. **14**C shows a cut-away view of the pin connection illustrated in FIGS. **14**A and **14**B;

FIG. **14**D shows an exploded view of a molded connection suitable for mounting an integration plate onto an implant;

FIG. **14**E shows the molded connection illustrated in FIG. **14**D with the components assembled;

FIG. **14**F shows a cut-away view of the molded connection illustrated in FIGS. **14**D and **14**E;

FIG. **14**G shows an exploded view of a fastener connection suitable for mounting an integration plate onto an implant;

FIG. **14**H shows the fastener connection illustrated in FIG. **14**G with the components assembled;

FIG. **14**I shows a cut-away view of the fastener connection illustrated in FIGS. **14**G and **14**H;

FIG. **14**J shows an exploded view of an undercut retention connection suitable for mounting an integration plate onto an implant;

FIG. **14**K shows the undercut retention connection illustrated in FIG. **14**J with the components assembled;

FIG. **14**L shows a cut-away view of the undercut retention connection illustrated in FIGS. **14**J and **14**K;

FIG. **14**M shows an exploded view of adhesive-undercut connection suitable for mounting an integration plate onto an implant;

FIG. **14**N shows the adhesive-undercut connection illustrated in FIG. **14**M with the components assembled;

FIG. **14**O shows a cut-away view of the adhesive-undercut connection illustrated in FIGS. **14**M and **14**N;

FIG. **14**P shows an exploded view of a press-fit connection suitable for mounting an integration plate onto an implant;

FIG. **14**Q shows the press-fit connection illustrated in FIG. **14**P with the components assembled;

FIG. **14**R shows a cut-away view of the press-fit connection illustrated in FIGS. **14**P and **14**Q;

FIG. **14**S shows an exploded view of a snap-fit connection suitable for mounting an integration plate onto an implant;

FIG. **14**T shows the snap-fit connection illustrated in FIG. **14**S with the components assembled;

FIG. **14**U shows a cut-away view of the snap-fit connection illustrated in FIGS. **14**S and **14**T;

FIG. **14**V shows an exploded view of an internal molded connection suitable for mounting an integration plate onto an implant;

FIG. **14**W shows the internal molded connection illustrated in FIG. **14**V with the components assembled;

FIG. **14**X shows a cut-away view of the internal molded connection illustrated in FIGS. **14**V and **14**W;

FIG. **15**A shows an example of a roughened topography capable of being created by coating a material onto the surface of an implant;

FIG. **15**B shows a flat implant surface capable of receiving a coated roughened topography;

FIG. **15**C shows a cut-away view of the coated roughened topography illustrated in FIG. **15**A;

FIG. **15**D shows an example of a roughened topography capable of being created by pressing a flexible foil onto the surface of an implant;

FIG. **15**E shows an exploded view of the flexible foil and implant surface;

FIG. **15**F shows an exploded side view of the flexible foil and implant illustrated in FIG. **15**E;

FIG. **16**A shows a side view of the representation of an integration plate having posts with one groove for mating with a corresponding tongue structure in an implant hole;

FIG. **16**B shows a bottom view of the representation illustrated in FIG. **16**A;

FIG. **16**C shows an example of a tongue-and-groove connection suitable for mounting an integration plate onto an implant;

FIG. **16**D shows a close-up view of the tongue-and-groove connection illustrated in FIG. **16**C;

FIG. **16**E shows a side view of a representation of an integration plate having posts with three grooves for mating with a corresponding tongue structure in an implant hole;

FIG. **16**F shows a bottom view of the representation illustrated in FIG. **16**E;

FIG. **16**G shows an example of a multiple tongue-and-groove connection suitable for mounting an integration plate onto an implant;

FIG. **16**H shows a close-up view of the multiple tongue-and-groove connection illustrated in FIG. **16**G;

FIG. **16**I shows a side view of a representation of an integration plate having posts with a rounded tongue structure for mating with a corresponding groove in an implant hole;

FIG. **16**J shows a bottom view of the representation illustrated in FIG. **16**I;

FIG. **16**K shows an example of a rounded tongue-and-groove connection suitable for mounting an integration plate onto an implant;

FIG. **16**L shows a close-up view of the rounded tongue-and-groove connection illustrated in FIG. **16**K;

FIG. **16**M shows a side view of a representation of an integration plate having posts with a diamond-shaped tongue structure for mating with a corresponding diamond-shaped groove in an implant hole;

FIG. **16**N shows a bottom view of the representation illustrated in FIG. **16**M;

FIG. **16**O shows an example of a diamond-shaped tongue-and-groove connection suitable for mounting an integration plate onto an implant;

FIG. **16**P shows a close-up view of the diamond-shaped tongue-and-groove connection illustrated in FIG. **16**O;

FIG. **16**Q shows a side view of a representation of an integration plate having posts with a threaded tongue structure for mating with a corresponding threaded groove in an implant hole;

FIG. **16**R shows a bottom view of the representation illustrated in FIG. **16**Q;

FIG. **16**S shows an example of a threaded tongue-and-groove connection suitable for mounting an integration plate onto an implant;

FIG. **16**T shows a close-up view of the threaded tongue-and-groove connection illustrated in FIG. **16**S;

FIG. **16**U shows a side view of a representation of an integration plate having posts with a plurality of a disc-shaped structures for mating with corresponding grooves in an implant hole;

FIG. **16**V shows a bottom view of the representation illustrated in FIG. **16**U;

FIG. **16**W shows an example of a disc-shaped tongue and groove connection suitable for mounting an integration plate onto an implant;

FIG. **16**X shows a close-up view of the disc-shaped tongue and groove connection illustrated in FIG. **16**W;

FIG. **16**Y shows a cut-away view of the disc-shaped tongue and groove connection illustrated in FIGS. **16**W and **16**X;

FIG. **17**A shows a side view of a representation of an integration plate having posts with vertically-oriented star-shaped tongue-and-groove structures for mating with corresponding vertically-oriented tongue-and-groove structures in an implant hole;

FIG. **17**B shows a bottom view of the representation illustrated in FIG. **17**A;

FIG. **17**C shows an example of a star-shaped tongue-and-groove connection suitable for mounting an integration plate onto an implant;

FIG. **17**D shows a close-up view of the star-shaped tongue-and-groove connection illustrated in FIG. **17**C;

FIG. **18**A shows an oval-shaped implant with a protruding anti-expulsion edge;

FIG. **18**B shows a close-up view of the protruding anti-expulsion edge of the implant illustrated in FIG. **18**A;

FIG. **18**C shows a rectangular-shaped implant with a protruding anti-expulsion edge oriented toward the posterior portion;

FIG. **18**D shows a close-up view of the protruding anti-expulsion edge of the implant illustrated in FIG. **18**C;

FIG. **18**E shows a perspective view of a curved-shaped implant with a protruding anti-expulsion edge oriented toward the posterior portion;

FIG. **18**F shows a close-up view of the protruding anti-expulsion edge of the implant perspective illustrated in FIG. **18**E;

FIG. **18**G shows another perspective view of the implant illustrated in FIG. **18**E;

FIG. **18**H shows a close-up view of the protruding anti-expulsion edge of the implant illustrated in FIG. **18**G;

FIG. **18**I shows a perspective view of a rectangular-shaped implant with a protruding anti-expulsion edge oriented toward one of the lateral sides;

FIG. **18**J shows another perspective view of the implant illustrated in FIG. **18**I;

FIG. **18**K shows a close-up view of the protruding anti-expulsion edge of the implant illustrated in FIG. **18**I;

FIG. **18**L shows a perspective view of a cervical implant with a protruding anti-expulsion edge;

FIG. **18**M shows a close-up view of the protruding anti-expulsion edge of the implant illustrated in FIG. **18**L;

FIG. **19**A shows a cut-away view of an implant with an integration plate having a protruding anti-expulsion edge;

FIG. **19**B shows a smooth joint between the integration plate and the implant illustrated in FIG. **19**A;

FIG. **20**A shows a side view of an integration plate having a protruding anti-expulsion edge;

FIG. **20**B shows a sharp edge configuration of the posterior edge of the integration plate illustrated in FIG. **20**A;

FIG. **20**C shows a chamfered edge configuration of the posterior edge of an integration plate;

FIG. **20**D shows a radiused edge configuration of the posterior edge of an integration plate;

FIG. **21** shows an example of an integration plate lordotic angle; and

FIG. **22** shows a example of an anti-expulsion edge angle.

DETAILED DESCRIPTION OF THE INVENTION

Certain embodiments of the invention may be especially suited for placement between adjacent human vertebral bodies. The implants of the invention may be used in procedures such as Anterior Lumbar Interbody Fusion (ALIF), Posterior Lumbar Interbody Fusion (PLIF), Transforaminal Lumbar Interbody Fusion (TLIF), and cervical fusion. Certain embodiments do not extend beyond the outer dimensions of the vertebral bodies.

The ability to achieve spinal fusion is directly related to the available vascular contact area over which fusion is desired, the quality and quantity of the fusion mass, and the stability of the interbody spinal implant. Interbody spinal implants, as now taught, allow for improved seating over the apophyseal rim of the vertebral body. Still further, interbody spinal implants, as now taught, better utilize this vital surface area over which fusion may occur and may better bear the considerable biomechanical loads presented through the spinal column with minimal interference with other anatomical or neurological spinal structures. Even further, interbody spinal implants, according to certain aspects of the invention, allow for improved visualization of implant seating and fusion assessment. Interbody spinal implants, as now taught, may also facilitate osteointegration with the surrounding living bone.

Anterior interbody spinal implants in accordance with certain aspects of the invention can be preferably made of a durable material such as stainless steel, stainless steel alloy, titanium, or titanium alloy, but can also be made of other durable materials such as, but not limited to, polymeric, ceramic, and composite materials. For example, certain embodiments of the invention may be comprised of a biocompatible, polymeric matrix reinforced with bioactive fillers, fibers, or both. Certain embodiments of the invention may be comprised of urethane dimethacrylate (DUDMA)/tri-ethylene glycol dimethacrylate (TEDGMA) blended resin and a plurality of fillers and fibers including bioactive fillers and E-glass fibers. Durable materials may also consist of any number of pure metals, metal alloys, or both. Titanium and its alloys are generally preferred for certain embodiments of the invention due to their acceptable, and desirable, strength and biocompatibility. In this manner, certain embodiments of the present interbody spinal implant may have improved structural integrity and may better resist fracture during implantation by impact. Interbody spinal implants, as now taught, may therefore be used as a distractor during implantation.

Referring now to the drawing, in which like reference numbers refer to like elements throughout the various figures that comprise the drawing, FIG. **1** shows a perspective view of a first embodiment of the interbody spinal implant **1** especially well adapted for use in an ALIF procedure.

The interbody spinal implant **1** includes a body having a top surface **10**, a bottom surface **20**, opposing lateral sides **30**, and opposing anterior **40** and posterior **50** portions. One or both of the top surface **10** and the bottom surface **20** has a roughened topography **80**. The roughened topography **80**, however, is distinct from the teeth provided on the surfaces of some conventional devices.

In some aspects, the interbody spinal implant **1** is substantially hollow and has a generally oval-shaped transverse cross-sectional area with smooth, rounded, or both smooth and rounded lateral sides **30** and posterior-lateral corners **52**. A substantially hollow implant **1** includes an implant **1** having at least about 33% of the interior volume of the implant **1** vacant. The implant **1** includes at least one vertical aperture **60** that extends the entire height of the implant body. The vertical aperture **60** may further define a transverse rim **100** having a greater posterior portion thickness **55** than an anterior portion thickness **45**.

In at least one embodiment, the opposing lateral sides **30** and the anterior portion **40** have a rim thickness **45** of about 5 mm, while the posterior portion **50** has a rim thickness **55** of about 7 mm. Thus, the rim posterior portion thickness **55** may allow for better stress sharing between the implant **1** and the adjacent vertebral endplates and helps to compensate for the weaker posterior endplate bone. In some aspects, the transverse rim **100** has a generally large surface area and contacts the vertebral endplate. The transverse rim **100** may act to better distribute contact stresses upon the implant **1**, and hence minimize the risk of subsidence while maximizing contact with the apophyseal supportive bone. It is also possible for the transverse rim **100** to have a substantially con-

stant thickness (e.g., for the anterior portion thickness **45** to be substantially the same as the posterior portion thickness **55**) or for the posterior portion **50** to have a rim thickness **55** less than that of the opposing lateral sides **30** and the anterior portion **40**. Some studies have challenged the characterization of the posterior endplate bone as weaker.

It is generally believed that the surface of an implant determines its ultimate ability to integrate into the surrounding living bone. Without being limited to any particular theory or mechanism of action, it is believed that the cumulative effects of at least implant composition, implant surface energy, and implant surface roughness play a major role in the biological response to, and osteointegration of, an implant device. Thus, implant fixation may depend, at least in part, on the attachment and proliferation of osteoblasts and like-functioning cells upon the implant surface. Still further, it appears that these cells attach more readily to relatively rough surfaces rather than smooth surfaces. In this manner, a surface may be bioactive due to its ability to facilitate cellular attachment and osteointegration. The surface roughened topography **80** may better promote the osteointegration of the implant **1**. The surface roughened topography **80** may also better grip the vertebral endplate surfaces and inhibit implant migration of the implant **1** upon placement and seating in a patient.

Accordingly, the implant **1** further includes the roughened topography **80** on at least a portion of its top **10** and bottom **20** surfaces for gripping adjacent bone and inhibiting migration of the implant **1**. FIG. **1** shows roughened topography **80** on an embodiment of the implant **1**.

The roughened topography **80** may be obtained through a variety of techniques including, without limitation, chemical etching, shot peening, plasma etching, laser etching, or abrasive blasting (such as sand or grit blasting). In at least one embodiment, the interbody spinal implant **1** may be comprised of titanium, or a titanium alloy, having the surface roughened topography **80**. The surfaces of the implant **1** are preferably bioactive.

In a preferred embodiment of the invention, the roughened topography **80** is obtained via the repetitive masking and chemical or electrochemical milling processes described in U.S. Pat. No. 5,258,098; U.S. Pat. No. 5,507,815; U.S. Pat. No. 5,922,029; and U.S. Pat. No. 6,193,762. Each of these patents is incorporated in this document by reference. Where the invention employs chemical etching, the surface is prepared through an etching process which utilizes the random application of a maskant and subsequent etching of the metallic substrate in areas unprotected by the maskant. This etching process is repeated a number of times as necessitated by the amount and nature of the irregularities required for any particular application. Control of the strength of the etchant material, the temperature at which the etching process takes place, and the time allotted for the etching process allow fine control over the resulting surface produced by the process. The number of repetitions of the etching process can also be used to control the surface features.

By way of example, an etchant mixture of nitric acid (HNO_3) and hydrofluoric (HF) acid may be repeatedly applied to a titanium surface to produce an average etch depth of about 0.53 mm. Interbody spinal implants **1**, in accordance with some preferred embodiments of the invention, may be comprised of titanium, or a titanium alloy, having an average surface roughness of about 100 μm. Surface roughness may be measured using a laser profilometer or other standard instrumentation.

In another example, chemical modification of the titanium implant surfaces can be achieved using HF and a combination of hydrochloric acid and sulfuric acid (HCl/H_2SO_4). In a dual acid etching process, the first exposure is to HF and the second is to HCl/H_2SO_4. Chemical acid etching alone of the titanium implant surface has the potential to greatly enhance osteointegration without adding particulate matter (e.g., hydroxyapatite) or embedding surface contaminants (e.g., grit particles).

The implant **1** may be shaped to reduce the risk of subsidence, and improve stability, by maximizing contact with the apophyseal rim of vertebral endplates. Embodiments may be provided in a variety of anatomical footprints having a medial-lateral width ranging from about 32 mm to about 44 mm. An interbody spinal implant **1** generally does not require extensive supplemental or obstructive implant instrumentation to maintain the prepared disc space during implantation. Thus, the interbody spinal implant **1** and associated implantation methods allow for larger-sized implants as compared with other size-limited interbody spinal implants known in the art. This advantage allows for greater medial-lateral width and correspondingly greater contact with the apophyseal rim. The implant **1** may also include an anti-expulsion edge **8** as described in more detail below.

As illustrated in FIG. **1**, the implant **1** has an opening **90** in the anterior portion **40**. In one embodiment the posterior portion **50** has a similarly shaped opening **90**. In some aspects, only the anterior portion **40** has the opening **90** while the posterior portion **50** has an alternative opening **92** (which may have a size and shape different from the opening **90**).

The opening **90** has a number of functions. One function is to facilitate manipulation of the implant **1** by the caretaker. Thus, the caretaker may insert a surgical tool into the opening **90** and, through the engagement between the surgical tool and the opening **90**, manipulate the implant **1**. The opening **90** may be threaded to enhance the engagement.

The implant **1** may further include at least one transverse aperture **70** that extends the entire transverse length of the implant body. The at least one transverse aperture **70** may provide improved visibility of the implant **1** during surgical procedures to ensure proper implant placement and seating, and may also improve post-operative assessment of implant fusion. Still further, the substantially hollow area defined by the implant **1** may be filled with cancellous autograft bone, allograft bone, DBM, porous synthetic bone graft substitute, BMP, or combinations of these materials (collectively, bone graft materials), to facilitate the formation of a solid fusion column within the spine of a patient.

Certain embodiments of the invention are particularly suited for use during interbody spinal implant procedures (or vertebral body replacement procedures) and may act as a final distractor during implantation, thus minimizing the instrument load upon the surgeon. For example, in such a surgical procedure, the spine may first be exposed via an anterior approach and the center of the disc space identified. The disc space is then initially prepared for implant insertion by removing vertebral cartilage. Soft tissue and residual cartilage may then also be removed from the vertebral endplates.

Vertebral distraction may be performed using trials of various-sized embodiments of the interbody spinal implant **1**. The determinatively sized interbody implant **1** may then be inserted in the prepared disc space for final placement. The distraction procedure and final insertion may also be performed under fluoroscopic guidance. The substantially hollow area within the implant body may optionally be filled, at least partially, with bone fusion-enabling materials such as, without limitation, cancellous autograft bone, allograft bone, DBM, porous synthetic bone graft substitute, BMP, or combinations of those materials. Such bone fusion-enabling material may be delivered to the interior of the interbody

spinal implant **1** using a delivery device mated with the opening **90** in the anterior portion **40** of the implant **1**. The interbody spinal implant **1** may be generally larger than those currently known in the art, and therefore have a correspondingly larger hollow area which may deliver larger volumes of fusion-enabling bone graft material. The bone graft material may be delivered such that it fills the full volume, or less than the full volume, of the implant interior and surrounding disc space appropriately.

As noted above, FIG. **1** shows a perspective view of one embodiment of the invention, the interbody spinal implant **1**, which is especially well adapted for use in an ALIF procedure. Other embodiments of the invention are better suited for PLIF, TLIF, or cervical fusion procedures. Specifically, FIGS. **2** and **3** show perspective views, from the front and rear, respectively, of an embodiment of an interbody spinal implant **101** especially well adapted for use in a PLIF procedure. The interbody spinal implant **101** includes a body having a top surface **110**, a bottom surface **120**, opposing lateral sides **130**, and opposing anterior **140** and posterior **150** portions. One or both of the top surface **110** and the bottom surface **120** has a roughened topography **180** for gripping adjacent bone and inhibiting migration of the implant **101**.

Certain embodiments of the interbody spinal implant **101** are substantially hollow and have a generally rectangular shape with smooth, rounded, or both smooth and rounded lateral sides and anterior-lateral corners. As best shown in FIG. **3**, the anterior portion **140** may have a tapered nose **142** to facilitate insertion of the implant **101**. To further facilitate insertion, the implant **101** has chamfers **106** at the corners of its posterior portion **150**. The chamfers **106** prevent the implant **101** from catching upon insertion, risking potential damage such as severed nerves, while still permitting the implant **101** to have an anti-expulsion edge **108**.

The implant **101** includes at least one vertical aperture **160** that extends the entire height of the implant body. The vertical aperture **160** further defines a transverse rim **200**. The size and shape of the vertical aperture **160** are carefully chosen to achieve a preferable design tradeoff for the particular application envisioned for the implant **101**. Specifically, the vertical aperture **160** seeks to maximize the surface area of the top surface **110** and the bottom surface **120** available proximate the anterior **140** and posterior **150** portions while maximizing both radiographic visualization and access to the bone graft material toward the center of the top **110** and bottom **120** surfaces. Thus, the size and shape of the vertical aperture **160** are predetermined by the application to which the implant **101** will be used.

In the particular example shown in FIGS. **2** and **3**, the width of the implant **101** between the two lateral sides **130** is approximately 9 mm. The shape of the vertical aperture **160** approximates, in cross section, that of an American football. The center of the vertical aperture **160**, which defines the maximum width of the vertical aperture **160**, is about 5 mm. Thus, the rim thickness **200** on either side of the vertical aperture **160** adjacent the center of the vertical aperture **160** is about 2 mm. These dimensions permit ample engagement between the bone graft material contained within the implant **101** and bone.

The vertical aperture **160** tapers from its center to its ends along a longitudinal distance of about 7.75 mm (thus, the total length of the vertical aperture **160** is about 15.5 mm). This shape leaves intact much of the rim thickness **200** in the areas around the ends of the vertical aperture **160**. These areas may allow for better stress sharing between the implant **101** and the adjacent vertebral endplates. Thus, the transverse rim **200** has a generally large surface area and contacts the vertebral endplate.

As illustrated in FIG. **2**, the implant **101** has an opening **190** in the posterior portion **150**. The opening **190** has a number of functions. One function is to facilitate manipulation of the implant **101** by the caretaker. Thus, the caretaker may insert a surgical tool into the opening **190** and, through the engagement between the surgical tool and the opening **190**, manipulate the implant **101**. The opening **190** may be threaded to enhance the engagement.

The implant **101** may also have an Implant Holding Feature (IHF) **194** instead of or in addition to the opening **190**. As illustrated in FIG. **2**, the IHF **194** is located proximate the opening **190** in the posterior portion **150**. In this particular example, the IHF **194** is a U-shaped notch. Like the opening **190**, the IHF **194** has a number of functions, one of which is to facilitate manipulation of the implant **101** by the caretaker. Other functions of the opening **190** and the IHF **194** are to increase visibility of the implant **101** during surgical procedures and to enhance engagement between bone graft material and adjacent bone.

The implant **101** may further include at least one transverse aperture **170**. Like the vertical aperture **160**, the size and shape of the transverse aperture **170** are carefully chosen (and predetermined) to achieve a preferable design tradeoff for the particular application envisioned for the implant **101**. Specifically, the transverse aperture **170** should have minimal dimensions to maximize the strength and structural integrity of the implant **101**. On the other hand, the transverse aperture **70** should have maximum dimensions to (a) improve the visibility of the implant **101** during surgical procedures to ensure proper implant placement and seating, and to improve post-operative assessment of implant fusion, and (b) to facilitate engagement between bone graft material and adjacent bone. The substantially hollow area defined by the implant **101** may be filled with bone graft materials to facilitate the formation of a solid fusion column within the spine of a patient.

As shown in FIGS. **2** and **3**, the transverse aperture **170** extends the entire transverse length of the implant body and nearly the entire height of the implant body. Thus, the size and shape of the transverse aperture **170** approach the maximum possible dimensions for the transverse aperture **170**.

The transverse aperture **170** may be broken into two, separate sections by an intermediate wall **172**. The section of the transverse aperture **170** proximate the IHF **194** is substantially rectangular in shape; the other section of the transverse aperture **170** has the shape of a curved arch. Other shapes and dimensions are suitable for the transverse aperture **170**. In particular, all edges of the transverse aperture **170** may be rounded, smooth, or both. The intermediate wall **172** may be made of the same material as the remainder of the implant **101** (e.g., metal), or it may be made of another material (e.g., PEEK) to form a composite implant **101**. The intermediate wall **172** may offer one or more of several advantages, including reinforcement of the implant **101** and improved bone graft containment.

The embodiment of the invention illustrated in FIGS. **2** and **3** is especially well suited for a PLIF surgical procedure. TLIF surgery is done through the posterior (rear) part of the spine and is essentially like an extended PLIF procedure. The TLIF procedure was developed in response to some of the technical problems encountered with a PLIF procedure. The main difference between the two spine fusion procedures is that the TLIF approach to the disc space is expanded by removing one

entire facet joint; a PLIF procedure is usually done on both sides by only taking a portion of each of the paired facet joints.

By removing the entire facet joint, visualization into the disc space is improved and more disc material can be removed. Such removal should also provide for less nerve retraction. Because one entire facet is removed, the TLIF procedure is only done on one side: removing the facet joints on both sides of the spine would result in too much instability. With increased visualization and room for dissection, one or both of a larger implant and more bone graft can be used in the TLIF procedure. Theoretically, these advantages can allow the spine surgeon to distract the disc space more and realign the spine better (re-establish the normal lumbar lordosis).

Although the TLIF procedure offers some improvements over a PLIF procedure, the anterior approach in most cases still provides the best visualization, most surface area for healing, and the best reduction of any of the approaches to the disc space. These advantages must be weighed, however, against the increased morbidity (e.g., unwanted aftereffects and postoperative discomfort) of a second incision. Probably the biggest determinate in how the disc space is approached is the comfort level that the spine surgeon has with an anterior approach for the spine fusion surgery. Not all spine surgeons are comfortable with operating around the great vessels (aorta and vena cava) or have access to a skilled vascular surgeon to help them with the approach. Therefore, choosing one of the posterior approaches for the spine fusion surgery is often a more practical solution.

The embodiment of the invention illustrated in FIGS. **4** and **5** is especially well suited when the spine surgeon elects a TLIF procedure. Many of the features of the implant **101***a* illustrated in FIGS. **4** and **5** are the same as those of the implant **101** illustrated in FIGS. **2** and **3**. Therefore, these features are given the same reference numbers, with the addition of the letter "a," and are not described further.

There are several differences, however, between the two embodiments. For example, unlike the substantially rectangular shape of the implant **101**, the implant **101***a* has a curved shape. Further, the chamfers **106** and anti-expulsion edge **108** of the implant **101** are replaced by curves or rounded edges for the implant **101***a*. Still further, the TLIF procedure often permits use of a larger implant **101***a* which, in turn, may affect the size and shape of the predetermined vertical aperture **160***a*.

The substantially constant 9 mm width of the transverse rim **200** of the implant **101** is replaced with a larger, curved transverse rim **200***a*. The width of the transverse rim **200***a* is 9 mm in the regions adjacent the anterior **140***a* and posterior **150***a* portions. That width gradually increases to 11 mm, however, near the center of the transverse rim **200***a*. The additional real estate provided by the transverse rim **200***a* (relative to the transverse rim **200**) allows the shape of the vertical aperture **160***a* to change, in cross section, from approximating a football to approximating a boomerang. Maintaining the thickness of the transverse rim **200***a* on either side of the vertical aperture **160***a* adjacent the center of the vertical aperture **160***a* at about 2 mm, similar to the dimensions of the implant **101**, the center of the vertical aperture **160***a*, which defines the maximum width of the vertical aperture **160***a*, is increased (from 5 mm for the implant **101**) to about 7 mm.

The implant **101***a* may also have a lordotic angle to facilitate alignment. The lateral side **130***a* depicted at the top of the implant **101***a* is preferably generally greater in height than the opposing lateral side **130***a*. Therefore, the implant **101***a* may better compensate for the generally less supportive bone found in certain regions of the vertebral endplate.

As shown in FIG. **4**, the transverse aperture **170***a* extends the entire transverse length of the implant body and nearly the entire height of the implant body. FIG. **5** highlights an alternative transverse aperture **170***a*. As illustrated in FIG. **5**, the transverse aperture **170***a* is broken into two, separate sections by an intermediate wall **172***a*. Thus, the dimensions of the transverse aperture **170***a* shown in FIG. **5** are much smaller than those for the transverse aperture **170***a* shown in FIG. **4**. The two sections of the alternative transverse aperture **170***a* are each illustrated as substantially rectangular in shape and extending nearly the entire height of the implant body; other sizes and shapes are possible for one or both sections of the alternative transverse aperture **170***a*.

The intermediate wall **172***a* may be made of the same material as the remainder of the implant **101***a* (e.g., metal), or it may be made of another material (e.g., PEEK) to form a composite implant **101***a*. It is also possible to extend the intermediate wall **172***a*, whether made of metal, PEEK, ultra-high molecular weight polyethylene (UHMWPE), or another material, to eliminate entirely the transverse aperture **170***a*. Given the reinforcement function of the intermediate wall **172***a*, the length of the vertical aperture **160***a* can be extended (as shown in FIG. **5**) beyond the top surface **110***a* and into the anterior portion **140***a* of the implant **101***a*.

The top surface **110***a* of the implant **101***a* need not include the roughened topography **180***a*. This difference permits the implant **101***a*, at least for certain applications, to be made entirely of a non-metal material. Suitable materials of construction for the implant **101***a* of such a design (which would not be a composite) include PEEK, hedrocel, UHMWPE, other radiolucent soft plastics, and additional materials as would be known town artisan.

The embodiments of the invention described above are best suited for one or more of the ALIF, PLIF, and TLIF surgical procedures. Another embodiment of the invention is better suited for cervical fusion procedures. This embodiment is illustrated in FIGS. **6** and **7** as the interbody spinal implant **201**.

Because there is not a lot of disc material between the vertebral bodies in the cervical spine, the discs are usually not very large. The space available for the nerves is also not that great, however, which means that even a small cervical disc herniation may impinge on the nerve and cause significant pain. There is also less mechanical load on the discs in the cervical spine as opposed to the load that exists lower in the spine. Among others, these differences have ramifications for the design of the implant **201**.

The implant **201** is generally smaller in size than the other implant embodiments. In addition, the lower mechanical load requirements imposed by the cervical application typically render a composite implant unnecessary. Therefore, the implant **201** is generally made entirely of metal (e.g., titanium) and devoid of other materials (e.g., PEEK).

With specific reference to FIG. **6**, the implant **201** includes a body having a top surface **210**, a bottom surface **220**, opposing lateral sides **230**, and opposing anterior **240** and posterior **250** portions. One or both of the top surface **210** and the bottom surface **220** has a roughened topography **280** for gripping adjacent bone and inhibiting migration of the implant **201**. The implant **201** is substantially hollow and has a generally oval shape with smooth, rounded, or both smooth and rounded edges.

The implant **201** includes at least one vertical aperture **260** that extends the entire height of the implant body. The vertical aperture **260** further defines a transverse rim **300**. The size and

shape of the vertical aperture **260** are carefully chosen to achieve a preferable design tradeoff for the particular application envisioned for the implant **201**. Specifically, the vertical aperture **260** seeks to maximize the surface area of the top surface **210** and the bottom surface **220**, to allow for better stress sharing between the implant **201** and the adjacent vertebral endplates, while maximizing access to the bone graft material provided within the implant **201**. Thus, the size and shape of the vertical aperture **260** are predetermined by the application.

As illustrated in FIG. **6**, the implant **201** has an opening **290** in the posterior portion **250**. The opening **290** has a number of functions. One function is to facilitate manipulation of the implant **201** by the caretaker. Thus, the caretaker may insert a surgical tool into the opening **290** and, through the engagement between the surgical tool and the opening **290**, manipulate the implant **201**. The opening **290** may be threaded to enhance the engagement.

The implant **201** may further include at least one transverse aperture **270**. Like the vertical aperture **260**, the size and shape of the transverse aperture **270** are carefully chosen (and predetermined) to achieve a preferable design tradeoff for the particular application envisioned for the implant **201**. For example, as shown in FIG. **6**, the transverse aperture **270** may extend the entire transverse length of the implant body and nearly the entire height of the implant body. Thus, the size and shape of the transverse aperture **270** approach the maximum possible dimensions for the transverse aperture **270**.

As illustrated in FIG. **6**, the implant **201** may be provided with a solid rear wall **242**. The rear wall **242** extends the entire width of the implant body and nearly the entire height of the implant body. Thus, the rear wall **242** essentially closes the anterior portion **240** of the implant **201**. The rear wall **242** may offer one or more of several advantages, including reinforcement of the implant **201** and improved bone graft containment. In the cervical application, it may be important to prevent bone graft material from entering the spinal canal.

Alternative shapes for the implant **201** are possible. As illustrated in FIG. **7**, for example, the implant **201** may have a generally box shape which gives the implant **201** increased cortical bone coverage. Like the implant **201** shown in FIG. **6**, the implant **201** shown in FIG. **7** has a curved transverse rim **300** in the area of the anterior portion **240**. The shape of the posterior portion **250** of the implant **201** is substantially flat, however, and the shape of the transverse rim **300** in the area of the posterior portion **250** is substantially square. Thus, the posterior portion **250** provides a face that can receive impact from a tool, such as a surgical hammer, to force the implant **201** into position.

The implant **201** may also have a lordotic angle to facilitate alignment. As illustrated in FIGS. **6** and **7**, the anterior portion **240** is preferably generally greater in height than the posterior portion **250**. Therefore, the implant **201** may better compensate for the generally less supportive bone found in certain regions of the vertebral endplate. As an example, four degrees of lordosis may be built into the implant **201** to help restore balance to the spine.

Certain embodiments of the implant **1**, **101**, **101***a*, and **201** are generally shaped (i.e., made wide) to maximize contact with the apophyseal rim of the vertebral endplates. They are designed to be impacted between the endplates, with fixation to the endplates created by an interference fit and annular tension. Thus, the implants **1**, **101**, **101***a*, and **201** are shaped and sized to spare the vertebral endplates and leave intact the hoop stress of the endplates. A wide range of sizes are possible to capture the apophyseal rim, along with a broad width of the peripheral rim, especially in the posterior region. It is expected that such designs will lead to reduced subsidence. As much as seven degrees of lordosis (or more) may be built into the implants **1**, **101**, **101***a*, and **201** to help restore cervical balance.

When endplate-sparing spinal implant **1**, **101**, **101***a*, and **201** seats in the disc space against the apophyseal rim, it should still allow for deflection of the endplates like a diaphragm. This means that, regardless of the stiffness of the spinal implant **1**, **101**, **101***a*, and **201**, the bone graft material inside the spinal implant **1**, **101**, **101***a*, and **201** receives load, leading to healthy fusion. The vertical load in the human spine is transferred though the peripheral cortex of the vertebral bodies. By implanting an apophyseal-supporting inter-body implant **1**, **101**, **101***a*, and **201**, the natural biomechanics may be better preserved than for conventional devices. If this is true, the adjacent vertebral bodies should be better preserved by the implant **1**, **101**, **101***a*, and **201**, hence reducing the risk of adjacent segment issues.

In addition, the dual-acid etched roughened topography **80**, **180**, **180***a*, and **280** of the top surface **30**, **130**, **130***a*, and **230** and the bottom surface **40**, **140**, **140***a*, and **240** along with the broad surface area of contact with the end-plates, is expected to yield a high pull-out force in comparison to conventional designs. As enhanced by the sharp edges **8** and **108**, a pull-out strength of up to 3,000 nt may be expected. The roughened topography **80**, **180**, **180***a*, and **280** creates a biological bond with the end-plates over time, which should enhance the quality of fusion to the bone. Also, the in-growth starts to happen much earlier than the bony fusion. The center of the implant **1**, **101**, **101***a*, and **201** remains open to receive bone graft material and enhance fusion. Therefore, it is possible that patients might be able to achieve a full activity level sooner than for conventional designs.

The spinal implant **1**, **101**, **101***a*, and **201** according to the invention offers several advantages relative to conventional devices. Such conventional devices include, among others, ring-shaped cages made of allograft bone material, threaded titanium cages, and ring-shaped cages made of PEEK or carbon fiber.

In some aspects, the implant **1**, **101**, **101***a*, and **201** includes an integration plate **82**, **182**, **182***a*, and **282**, for example, as shown in FIG. **8**A-FIG. **10** and FIG. **12**. In addition, a lateral implant **301** having a substantially rectangular shape may include an integration plate **382**, for example, as shown in FIG. **11**. The lateral implant **301** comprises the same general features as the implant **1**, **101**, **101***a*, and **201**, including a top surface **310**, a bottom surface **320**, lateral sides **330**, opposing anterior **340** and posterior **350** portions, an opening **390**, as well as at least one vertical aperture **360** that extends the entire height of the implant body, and one or more transverse apertures **370** that extend the entire transverse length of the implant body.

The integration plate, shown in the drawings as component **82** (FIG. **8**A and FIG. **8**B), **182** (FIG. **10**), **182***a* (FIG. **9**), **382** (FIG. **11**), and **282** (FIG. **12**), respectively, includes the roughened surface topography **80**, **180**, **180***a*, **280**, and **380**, and is connectable to either or both of the top surface **10**, **110**, **110***a*, **210**, and **310** or bottom surface **20**, **120**, **120***a*, **220**, and **320**. The integration plate **82**, **182**, **182***a*, **282**, and **382** includes a top surface **81**, **181**, **181***a*, **281**, and **381**; a bottom surface **83**, **183**, **183***a*, **283**, and **383**; an anterior portion **41**, **141**, **141***a*, **241**, and **341**; a posterior portion **51**, **151**, **151***a*, **251**, and **351**; and at least one vertical aperture **61**, **161**, **161***a*, **261**, and **361**. The anterior portion **41**, **141**, **141***a*, **241**, and **341** preferably aligns with the anterior portion **40**, **140**, **140***a*, **240**, and **340** of the main body of the implant **1**, **101**, **101***a*, **201**, and **301**, respectively, and the posterior portion **51**, **151**,

151*a*, 251, and 351 aligns with the posterior portion 50, 150, 150*a*, 250, and 350 of the main body of the implant 1, 101, 101*a*, 201, and 301, respectively. The vertical aperture 61, 161, 161*a*, 261, and 361 preferably aligns with the vertical aperture 60, 160, 160*a*, 260, and 360 of the main body of the implant 1, 101, 101*a*, 201, and 301, respectively. Thus, the integration plate vertical aperture 61, 161, 161*a*, 261, and 361 and the body vertical aperture 60, 160, 160*a*, 260, and 360 preferably comprise substantially the same shape.

The top surface 81, 181, 181*a*, 281, and 381 of the integration plate 82, 182, 182*a*, 282, and 382 preferably comprises the roughened topography 80, 180, 180*a*, 280, and 380. The bottom surface 83, 183, 183*a*, 283, and 383 of the integration plate 82, 182, 182*a*, 282, and 382 preferably comprises a reciprocal connector structure, such as a plurality of posts 84, 184, 184*a*, 284, and 384 that align with and insert into a corresponding connector structure such as a plurality of holes 12, 112, 112*a*, 212, and 312 on the top surface 10, 110, 110*a*, 210, and 310 and/or bottom surface 20, 120, 120*a*, 220, and 320 of the main body of the implant 1, 101, 101*a*, 201, and 301, respectively, and thus facilitate the connection between the integration plate 82, 182, 182*a*, 282, and 382 and the main body of the implant 1, 101, 101*a*, 201, and 301. Thus, integration plates 82, 182, 182*a*, 282, and 382 with different sizes, shapes, or features may be used in connection with the implant 1, 101, 101*a*, 201, and 301, for example, to accommodate attributes of the spine of the patient to which the implant 1, 101, 101*a*, 201, and 301 is to be implanted. Among these different sizes, shapes, and features are lordotic angles; anti-expulsion edges 8, 108, 108*a*, 208, and 308; and anti-expulsion angles as described throughout this specification.

The implant 1, 101, 101*a*, 201, and 301 is configured to receive the integration plate 82, 182, 182*a*, 282, and 382, respectively. Thus, for example, the top surface 10, 110, 110*a*, 210, and 310 and/or bottom surface 20, 120, 120*a*, 220, and 320 of the implant 1, 101, 101*a*, 201, and 301 may be recessed, and comprise a plurality of holes 12, 112, 112*a*, 212, and 312 that mate with the plurality of posts 84, 184, 184*a*, 284, and 384 on the bottom surface 83, 183, 183*a*, 283, and 383 of the integration plate 82, 182, 182*a*, 282, and 382. Thus, the plurality of posts 84, 184, 184*a*, 284, and 384 are inserted into the plurality of holes 12, 112, 112*a*, 212, and 312.

FIG. 8A and FIG. 8B show that the top surface 10 is recessed and comprises a plurality of holes 12, but the recessed bottom surface 20 and its holes 12 are not shown. FIG. 9 shows that the top surface 110*a* is recessed and comprises a plurality of holes 112*a*, but the recessed bottom surface 120*a* and its holes 112*a* are not shown. FIG. 10 shows that the top surface 110 is recessed and comprises a plurality of holes 112, but the recessed bottom surface 120 and its holes 112 are not shown. FIG. 11 shows that the top surface 310 is recessed and comprises a plurality of holes 312, but the recessed bottom surface 320 and its holes 312 are not shown. FIG. 12 shows that the top surface 210 is recessed and comprises a plurality of holes 212, but the recessed bottom surface 220 and its holes 212 are not shown. The recess may be at a depth D, and the recess depth D preferably is uniform throughout the top surface 10, 110, 110*a*, 210, and 310 and/or bottom surface 20, 120, 120*a*, 220, and 320.

The recess depth D preferably corresponds to a thickness T of the integration plate 82, 182, 182*a*, 282, and 382. Thus, in some aspects, the depth D and thickness T are the same so that once the integration plate 82, 182, 182*a*, 282, and 382 and body of the implant 1, 101, 101*a*, 201, and 301, respectively, are placed together, the top surface 10, 110, 110*a*, 210, and 310 and/or bottom surface 20, 120, 120*a*, 220, and 320 of the implant 1, 101, 101*a*, 201, and 301 is substantially even, at least at the seam/junction between the integration plate 82, 182, 182*a*, 282, and 382 and the top surface 10, 110, 110*a*, 210, and 310 or bottom surface 20, 210, 120*a*, 220, and 320. In some embodiments, the posterior portion 51, 151, 151*a*, 251, and 351 and the anterior portion 41, 141, 141*a*, 241, and 341 of the integration plate 82, 182, 182*a*, 282, and 382 have different thicknesses such that the anterior portion 41, 141, 141*a*, 241, and 341 has a greater thickness than the thickness T of the posterior portion 51, 151, 151*a*, 251, and 351. For example, as shown in FIG. 13A, the anterior portion 41 has a greater thickness T' than the thickness T of the posterior portion 51.

The recess depth D, the thickness T, and the thickness T' may each independently be from about 0.1 mm to about 10 mm. In preferred aspects, the recess depth D, the thickness T, and the thickness T' may each independently be from about 1 mm to about 5 mm. Thus, for example, either the recess depth D, the thickness T, and the thickness T' may be selected from about 0.1 mm, about 0.25 mm, about 0.5 mm, about 0.75 mm, about 1 mm, about 1.25 mm, about 1.5 mm, about 1.75 mm, about 2 mm, about 2.25 mm, about 2.5 mm, about 2.75 mm, about 3 mm, about 3.25 mm, about 3.5 mm, about 3.75 mm, about 4 mm, about 4.25 mm, about 4.5 mm, about 4.75 mm, about 5 mm, 5.5 mm, about 6 mm, about 6.5 mm, about 7 mm, about 75 mm, or about 8 mm.

Recessing the top surface 10, 110, 110*a*, 210, and 310 or bottom surface 20, 120, 120*a*, 220, and 320 exposes a ridge 11, 111, 111*a*, 211, and 311 against which the anterior portion 41, 141, 141*a*, 241, and 341, posterior portion 51, 151, 151*a*, 251, and 251 or lateral side of the integration plate 82, 182, 182*a*, 282, and 382 may be seated when brought together with the implant 1, 101, 101*a*, 201, and 301.

The integration plate 82, 182, 182*a*, 282, and 382 may be used with an implant suitable for ALIF (e.g., implant 1, integration plate 82), PLIF (e.g., implant 101, integration plate 182), or TLIF fusion (e.g., implant 101*a*, integration plate 182*a*); may be used with an implant suitable for cervical fusion (e.g., implant 201, integration plate 282); and may be used with an implant suitable for lateral lumbar insertion (e.g., implant 301, integration plate 382). The integration plate 82, 182, 182*a*, 282, and 382 is preferably metal, and may be used with a metal implant. The metal integration plate 82, 182, 182*a*, 282, and 382 may also be used with a molded plastic or polymer implant, or a composite implant. In some aspects, the integration plate 82, 182, 182*a*, 282, and 382 may also comprise a plastic, polymeric, or composite material.

The reciprocal connector such as the post 84, 184, 184*a*, 284, and 384 preferably is secured within the connector of the body such as the hole 12, 112, 112*a*, 212, and 312 to mediate the connection between the integration plate 82, 182, 182*a*, 282, and 382 and the implant 1, 101, 101*a*, 201, and 301. The connection should be capable of withstanding significant loads and shear forces when implanted in the spine of the patient. The connection between the post 84, 184, 184*a*, 284, and 384 and the hole 12, 112, 112*a*, 212, and 312 may comprise a friction fit. For example, FIG. 13A shows a cut-away side view of the implant 1 having an integration plate 82 on the top 10 and bottom 20 portions, with the posts 84 inserted into the holes 12. FIG. 13B shows a close up view of the post 84 and hole 12 connection. In some aspects, the reciprocal connector such as the post 84, 184, 184*a*, 284, and 384 and the connector of the body such as the hole 12, 112, 112*a*, 212, and 312 have additional compatible structures and features to further strengthen the connection between the integration plate 82, 182, 182*a*, 282, and 382 and the implant 1, 101,

101*a*, 201, and 301. Non-limiting examples of such structures and features are illustrated in FIGS. 14-17.

The structures and features may be on either or both of the integration plate 82, 182, 182*a*, 282, and 382 and the main body of the implant 1, 101, 101*a*, 201, and 301. In general, the structures include fasteners, compatibly shaped joints, compatibly shaped undercuts, and/or other suitable connectors having different shapes, sizes, and configurations. For example, a fastener may include a pin, screw, bolt, rod, anchor, snap, clasp, clip, clamp, or rivet. In some aspects, an adhesive may be used to further strengthen any of the integration plate 82, 182, 182*a*, 282, and 382 and implant 1, 101, 101*a*, 201, and 301 connections described in this specification. An adhesive may comprise a cement, glue, polymer, epoxy, solder, weld, or other suitable binding material.

As shown in FIGS. 14A-14C, an integration plate 482 (shown in the drawings as a box only for illustration purposes) having a roughened surface topography 480 may comprise one or more reciprocal connectors such as one or more posts 484 each having a bore 485 extending through a horizontal plane. The post 484 is inserted into a connector such as a hole 412 through the implant 401 (also shown in the drawings as a box only for illustration purposes). A fastener 486, which may be a pin 486, is inserted through the bore 485 (FIG. 14A), thereby preventing the post 484 from being disengaged from the hole 412 (FIG. 14B). In some aspects, the pin 486 is also threaded through a second bore 487 that passes through the walls of the implant 401 itself, although it is preferable that the implant 401 does not include a second bore 487 through its walls and that the bore 485 is accessible from the space inside of the implant 401. It is to be understood that components numbered in the four hundred series are shown for illustration purposes, and correspond to features of each implant 1, 101, 101*a*, 201, and 301; for example, post 484 is representative of post 84, 184, 184*a*, 284, and 384.

FIGS. 14D-F show another embodiment of the integration plate 482 comprising a plurality of bores 485 present on and having an opening accessible from the bottom surface 483 of the integration plate 482. The bores 485 mate with a plurality of fasteners 486, which may comprise rods 486 (FIG. 14D) integral with or otherwise attached to the top surface 410 or bottom surface (not shown) of the implant 401. For example, the rods 486 may be molded as upward-facing extensions of the top surface 410 (FIG. 14F). The rods 486 may be snap-fit into the bores 485 through the opening (FIG. 14F), in which case the opening may be slightly smaller in width than the bores 485 and rods 486, though still allowing the rods 486 to pass through the opening and into the bores 485.

In some embodiments, such as those shown in FIGS. 14G-I, the integration plate 482 comprises one or more bores 485 in a vertical plane, extending through the integration plate 482, through which a fastener 486, which may be a screw or bolt 486, may be inserted. The screw or bolt 486 may extend into a hole 412 extending at least partially into the implant 401, and the hole 412 and screw or bolt 486 preferably comprise compatible screw threads 415 (FIG. 14I). Tightening of the screw or bolt 486 secures the integration plate 482 in place on the implant 401 (FIG. 14H). In some aspects, for example, where the implant 401 is comprised of a plastic or polymeric material, the hole 412 may not be present, and the screw or bolt 486 may be screwed directly into the plastic or polymeric material, with the screw threads tightly gripping the plastic or polymeric material to form the connection. The integration plate may have a roughened topography 480.

The bottom surface 483 of the integration plate 482 may comprise undercuts in shapes that form a tight junction with compatible shapes on the implant 401. For example, as shown in FIGS. 14J-L, the bottom surface 483 may comprise a dovetail joint, or bevel, or taper that fits with a counterpart dovetail joint, bevel, or taper on the implant 401 (FIG. 14L). The shape of each of the integration plate 482 undercuts (FIG. 14J) and counterpart undercuts on the implant 401 (FIG. 14L) are such that the connection forms a joint between the implant 401 and integration plate 482, and that this joint is established and retained with a tight tolerance (FIG. 14K).

As shown in FIGS. 14M-O, the integration plate 482 comprising a plurality of bores 485 present on and having an opening accessible from the bottom surface 483 of the integration plate 482 may mate with a plurality of fasteners 486, which may comprise rod-shaped adhesives 486, or which may comprise rods 486 coated or otherwise impregnated with an adhesive (FIG. 14M). A rod-shaped adhesive 486 may comprise an hourglass-shaped cross section, with one side capable of being snap-fit into the bores 485 through the opening, and with the other side capable of being snap-fit into bores 487 in the top surface 410 of the implant 401. In this manner, the rod-shaped adhesive 486 may bridge the implant 401 and integration plate 482 together as shown in FIG. 14O. In an alternative embodiment, the implant 401 comprises rods 486 integral with or otherwise attached to the top surface 410 or bottom surface (not shown) of the implant 401, for example, as illustrated in FIG. 14D, and these rods 486 may be coated with an adhesive that joins the rods 486 together with the sidewalls of the bores 485 in the integration plate 482.

An adhesive may directly join the integration plate 482 and the implant 401 together. For example, the adhesive may be applied to the bottom surface 483 of the integration plate 482 or the top surface 410 of the implant 401, and each part bridged together with the adhesive (not illustrated). In some aspects, the bottom surface 483 of the integration plate 482 may include undercuts in shapes that form a tight junction with compatible shapes on the implant 401. For example, an adhesive may be applied to undercuts and joints as shown in FIG. 14J to strengthen the connection between the integration plate 482 and the implant 401. FIGS. 14P-R show an alternative embodiment of undercuts on the integration plate 482 that form a connection with corresponding cuts on the implant 401, and an adhesive may be applied to strengthen this connection.

The integration plate 482 may be connected to the implant 401 with a snap-fit connection, for example, as shown in FIGS. 14S-U. The integration plate 482 may comprise one or more bores 485 extending vertically through the integration plate 482, through which a fastener 486, which may be a rivet, snap or snap button 486, may be inserted (FIG. 14S). The rivets 486, snaps 486, or snap buttons 486 may be integral with or otherwise attached to the top surface 410 (FIG. 14S) or bottom surface (not shown) of the implant 401. For example, the rivets 486, snaps 486, or snap buttons 486 may be molded as upward-facing extensions of the top surface 410 (FIG. 14U). In some preferred aspects, the rivets 486, snaps 486, or snap buttons 486 comprise a head portion with a diameter slightly larger than and a shaft portion with a diameter slightly smaller than the diameter of the bores 485. In some preferred aspects, at least the head portion of the rivets 486, snaps 486, or snap buttons 486 is fabricated of a material that allows the head portion to compress slightly and pass through the bores 485 when the integration plate 482 is pressed toward the implant 401, after which the head portion re-expands such that the rivets 486, snaps 486, or snap buttons 486 cannot be disengaged from the bores 485 (FIG. 14T).

In some embodiments, an anchor plate 486 enhances the connection between the posts 484 of the integration plate 482

and the holes **412** of the implant **401**, as shown in FIGS. **14**V-**14**X. For example, the top surface **410** of the implant **401** may be molded in a shape or configuration into which an anchor plate **486** may be inserted (FIG. **14**X), or the anchor plate **486** may otherwise be adhered to the implant **401**. The anchor plate **486** may comprise one or more bores **485** through which the post **484** may pass through (FIG. **14**V). The integration plate **482**, anchor plate **486**, and implant **401** may be pressed together to form a tight junction that maintains the connection of the integration plate **482** to the implant **401**.

The foregoing describes various non-limiting examples of how an integration plate **82**, **182**, **182***a*, **282**, and **382** may be joined together with an implant **1**, **101**, **101***a*, **201**, and **301**. One non-limiting objective of this approach is to provide a roughened topography **80**, **180**, **180***a*, **280**, and **380** to the surface of the implant **1**, **101**, **101***a*, **201**, and **301**. The roughened topography **80**, **180**, **180***a*, **280**, and **380** can be established on the integration plate **82**, **182**, **182***a*, **282**, and **382** according to any suitable methodology, including those described or exemplified in this specification. The roughened topography **80**, **180**, **180***a*, **280**, and **380** may also be provided by coating the implant **1**, **101**, **101***a*, **201**, and **301** or the integration plate **82**, **182**, **182***a*, **282**, and **382** with a roughened topography material (e.g., FIGS. **15**A-F).

For example, in some aspects, a material such as metal filings, shavings, or fine metal particles or powder, or fine plastic or polymeric particles may be laid onto the top surface **10**, **110**, **110***a*, **210**, and **310** or bottom surface **20**, **120**, **120***a*, **220**, and **320** of the implant **1**, **101**, **101***a*, **201**, and **301** or onto the top surface **81**, **181**, **181***a*, **281**, and **381** of the integration plate **82**, **182**, **182***a*, **282**, and **382** according to any suitable method. In some aspects, an adhesive may be used to affix the material to the implant **1**, **101**, **101***a*, **201**, and **301** or integration plate **82**, **182**, **182***a*, **282**, and **382**. Plastic or polymeric materials may be spray-coated, airlaid, or melt-blown onto the implant **1**, **101**, **101***a*, **201**, and **301** or integration plate **82**, **182**, **182***a*, **282**, and **382**. The materials may be adhered directly, for example, by at least partially melting the particles such that they fuse to the desired surface when they cool. Metal materials may be cold sprayed or thermal sprayed onto the implant **1**, **101**, **101***a*, **201**, and **301** or integration plate **82**, **182**, **182***a*, **282**, and **382** according to any suitable technique.

FIGS. **15**A-C show a non-limiting embodiment of a roughened topography **480** coated onto the top surface **410** of the implant **401** (shown in the drawings as a box only for illustration purposes). The roughened topography **480** may also be coated onto the bottom surface of the implant **401** (not shown). The roughened topography **480** may be coated onto the top surface **481** of the integration plate **482** (not shown).

In some alternative aspects, a backing **479** comprising a roughened topography **480** may be laid onto the top surface **410** of the implant **401** as shown in FIGS. **15**D-F. For example, the backing **479** may comprise a foil, mesh, screen, or other suitable material, preferably comprising a metal, that is sufficiently flexible such that it may conform to the shapes and contours of the top surface **410** of the implant **401** (FIG. **15**E and FIG. **15**F). In this same manner, the backing **479** may be laid onto the top surface **481** of the integration plate **482** (not shown). An adhesive may be used to join the backing **479** to the top surface **410** of the implant **401** or top surface **481** of the integration plate **482**. The backing **479** may be soldered, melted, or welded to the top surface **410** of the implant **401** or top surface **481** of the integration plate **482**.

A preferred connection between the integration plate **82**, **182**, **182***a*, **282**, and **382** and the implant **1**, **101**, **101***a*, **201**, and **301** includes the post **84**, **184**, **184***a*, **284**, and **384** and hole **12**, **112**, **112***a*, **212**, and **312** connection, without additional fasteners required to maintain this connection, for example, through a friction fit. In some embodiments the post **84**, **184**, **184***a*, **284**, and **384** and hole **12**, **112**, **112***a*, **212**, and **312** include different interlocking joints to strengthen the connection between them. These interlocking joints preferably include different configurations of a basic tongue-and-groove joint, for example, as shown in FIGS. **16** and **17**.

In some embodiments, an integration plate **482** (shown in the drawings as a box only for illustration purposes) having a roughened surface topography **480** may comprise one or more posts **484** (FIG. **16**A), each comprising a groove **488** (FIG. **16**A and FIG. **16**B). The posts **484** may include more than one groove **488**, including two, three, four, five, six, seven, eight or more grooves **488**. FIG. **16**E and FIG. **16**F show a non-limiting example of a post **484** with three groves **488**.

Each groove **488** preferably mates with a corresponding tongue **489** in the hole **412** of the implant **401**. For example, as shown in FIGS. **16**C and **16**D, each hole **412** may include one tongue **489** that forms a connection with one groove **488** in the post **484**. The holes **412** may include more than one tongue **489**, including two, three, four, five, six, seven, eight or more tongues **489**. FIGS. **16**G and **16**H show a non-limiting example of each hole **412** including three tongues **489**.

When the integration plate **482** is pressed together with the implant **401** (shown in the drawings as a box only for illustration purposes), the post **484** is inserted into its corresponding hole **412**, and each tongue **489** is inserted into its corresponding groove **488**. In this regard, it is preferable that the material used to fabricate the tongue **489** is sufficiently flexible to allow the wider portions of the post **484** that flank each groove **488** to pass over the tongue **489** so that the tongue **489** can fit within its groove **488**, yet is sufficiently rigid to prevent disengagement of the tongue **489** from the groove **488** once the integration plate **482** and implant **481** are together.

In some embodiments, the location of the tongue **489** and groove **488** on the post **484** and hole **412** are reversed. For example, the tongue **489** may be present on the post **484** and the groove **488** may be present on the hole **412**. FIGS. **16**I-X show examples of a post **484** and hole **412** connection in which the post **484** comprises one or more tongues **489** that fit within one or more grooves **488** in the sidewalls of the hole **412**.

The tongue **489** may comprise a round shape (FIGS. **16**I and **16**J), and may thus mate with a groove **488** having a reciprocal round shape (FIGS. **16**K and **16**L). The tongue **489** may comprise a triangular shape (FIGS. **16**E and **16**F), and may thus mate with a groove **488** having a reciprocal triangular shape (FIGS. **16**G and **16**H). The tongue **489** may comprise a diamond shape (FIGS. **16**M and **16**N), and may thus mate with a groove **488** having a reciprocal diamond shape (FIGS. **16**O and **16**P). The tongue **489** may comprise a threaded shape (FIGS. **16**Q and **16**R), and may thus mate with a groove **488** having a reciprocal threaded shape (FIGS. **16**S and **16**T). The tongue **489** may comprise a disc shape (FIGS. **16**U and **16**V), and may thus mate with a groove **488** having a reciprocal disc shape (FIGS. **16**W and **16**X). A cross-section of such a configuration is shown in FIG. **16**Y.

Each hole may include one groove **488** that forms a connection with one tongue **489** on the post **484**. The holes **412** may include more than one groove **488**, including two, three, four, five, six, seven, eight or more grooves **488**. The post **484** may include more than one tongue **489**, including two, three, four, five, six, seven, eight or more tongues **489**.

When the integration plate **482** is pressed together with the implant **401**, the post **484** is inserted into its corresponding

hole **412**, and the tongue **489** is inserted into its corresponding groove **488**. It is preferable that the material out of which the tongue **489** is fabricated is sufficiently flexible to allow the tongue **489** to pass over the wider portions of the hole **412** that flank each groove **488** so that the tongue **489** can fit within its groove **488**, yet is sufficiently rigid to prevent disengagement of the tongue **489** from the groove **488** once the integration plate **482** and implant **481** are together.

Whether on the post **484** or the hole **412**, the tongue **489** and groove **488** may comprise any suitable shape, and preferably, each has a shape compatible with its counterpart. The shape may be regular or irregular. Each of the tongue **489** and groove **488** may comprise a substantially round, triangular, diamond, square, dovetail, or polygonal shape. Optionally, an adhesive may be used to further strengthen the connection between the tongue **489** and the groove **488**.

FIGS. **16**A-Y show non-limiting examples of a tongue **489** and groove **488** connection in which each tongue **489** and groove **488** are oriented in a horizontal plane. In some aspects, the tongue **489** and groove **488** may be oriented in a vertical plane. For example, as shown in FIGS. **17**A-D, an integration plate **482** may comprise one or more posts **484**, with each post **484** comprising one or more vertically oriented tongues **489**. Each vertically oriented tongue **489** preferably mates with a corresponding vertically oriented groove **488** in the hole **412**. The posts **484** may, for example, have a star shape (FIGS. **17**A and **17**B) with the edges of the stars forming both tongues **489** and grooves **488**, and the holes **412** may have a reciprocal star shape (FIGS. **17**C and **17**D) with the edges of the stars forming reciprocal grooves **488** and tongues **489**.

When the integration plate **482** is pressed together with the implant **401** (shown in the drawings as a box only for illustration purposes), the post **484** is inserted into its corresponding hole **412**, and the vertically oriented tongue **489** is inserted into its corresponding vertically oriented groove **488**. Each post **484**, including its vertically oriented tongues **489**, preferably has a wider diameter than the corresponding hole **412**, including the vertically oriented grooves **488**, such that a tight friction fit is established and maintained between the post **484** and the hole **412**. Optionally, an adhesive may be used to further strengthen the connection.

Example Surgical Methods

The following examples of surgical methods are included to more clearly demonstrate the overall nature of the invention. These examples are exemplary, not restrictive, of the invention.

Certain embodiments of the invention are particularly suited for use during interbody spinal implant procedures currently known in the art. For example, the disc space may be accessed using a standard mini open retroperitoneal laparotomy approach. The center of the disc space is located by AP fluoroscopy taking care to make sure the pedicles are equidistant from the spinous process. The disc space is then incised by making a window in the annulus for insertion of certain embodiments of the spinal implant **1** (a 32 or 36 mm window in the annulus is typically suitable for insertion). The process according to the invention minimizes, if it does not eliminate, the cutting of bone. The endplates are cleaned of all cartilage with a curette, however, and a size-specific rasp (or broach) may then be used.

Use of a rasp preferably substantially minimizes or eliminates removal of bone, thus substantially minimizing or eliminating impact to the natural anatomical arch, or concavity, of the vertebral endplate while preserving much of the apophyseal rim. Preservation of the anatomical concavity is particularly advantageous in maintaining biomechanical integrity of the spine. For example, in a healthy spine, the transfer of compressive loads from the vertebrae to the spinal disc is achieved via hoop stresses acting upon the natural arch of the endplate. The distribution of forces, and resultant hoop stress, along the natural arch allows the relatively thin shell of subchondral bone to transfer large amounts of load.

During traditional fusion procedures, the vertebral endplate natural arch may be significantly removed due to excessive surface preparation for implant placement and seating. This is especially common where the implant is to be seated near the center of the vertebral endplate or the implant is of relatively small medial-lateral width. Breaching the vertebral endplate natural arch disrupts the biomechanical integrity of the vertebral endplate such that shear stress, rather than hoop stress, acts upon the endplate surface. This redistribution of stresses may result in subsidence of the implant into the vertebral body.

Preferred embodiments of the surgical method minimize endplate bone removal on the whole, while still allowing for some removal along the vertebral endplate far lateral edges where the subchondral bone is thickest. Still further, certain embodiments of the interbody spinal implant **1**, **101**, **101***a*, **201**, and **301** include smooth, rounded, and highly radiused posterior portions and lateral sides which may minimize extraneous bone removal for endplate preparation and reduce localized stress concentrations. Thus, interbody surgical implant **1**, **101**, **101***a*, **201**, and **301** and methods of using it are particularly useful in preserving the natural arch of the vertebral endplate and minimizing the chance of implant subsidence.

Because the endplates are spared during the process of inserting the spinal implant **1**, **101**, **101***a*, **201**, and **301**, hoop stress of the inferior and superior endplates is maintained. Spared endplates allow the transfer of axial stress to the apophasis. Endplate flexion allows the bone graft placed in the interior of the spinal implant **1** to accept and share stress transmitted from the endplates. In addition, spared endplates minimize the concern that BMP might erode the cancellous bone.

Interbody spinal implant **1** is durable and can be impacted between the endplates with standard instrumentation. Therefore, certain embodiments of the invention may be used as the final distractor during implantation. In this manner, the disc space may be under-distracted (e.g., distracted to some height less than the height of the interbody spinal implant **1**) to facilitate press-fit implantation. Further, certain embodiments of the current invention having a smooth and rounded posterior portion (and lateral sides) may facilitate easier insertion into the disc space. Still further, those embodiments having a surface roughened topography **80** may lessen the risk of excessive bone removal during distraction as compared to implants having teeth, ridges, or threads currently known in the art even in view of a press-fit surgical distraction method. Nonetheless, once implanted, the interbody surgical implant **1** may provide secure seating and prove difficult to remove. Thus, certain embodiments of the interbody spinal implant **1**, **101**, **101***a*, **201**, and **301** may maintain a position between the vertebral endplates due, at least in part, to resultant annular tension attributable to press-fit surgical implantation and, post-operatively, improved osteointegration at the top surface **10**, **110**, **110***a*, **210**, and **310**; the bottom surface **20**, **120**, **120***a*, **220**, and **320**; or both surfaces.

Surgical implants and methods tension the vertebral annulus via distraction. These embodiments and methods may also restore spinal lordosis, thus improving sagittal and coronal

alignment. Implant systems currently known in the art require additional instrumentation, such as distraction plugs, to tension the annulus. These distraction plugs require further tertiary instrumentation, however, to maintain the lordotic correction during actual spinal implant insertion. If tertiary instrumentation is not used, then some amount of lordotic correction may be lost upon distraction plug removal. Interbody spinal implant **1**, according to certain embodiments of the invention, is particularly advantageous in improving spinal lordosis without the need for tertiary instrumentation, thus reducing the instrument load upon the surgeon. This reduced instrument load may further decrease the complexity, and required steps, of the implantation procedure.

Certain embodiments of the spinal implant **1**, **101**, **101***a*, **201**, and **301** may also reduce deformities (such as isthmic spondylolythesis) caused by distraction implant methods. Traditional implant systems require secondary or additional instrumentation to maintain the relative position of the vertebrae or distract collapsed disc spaces. In contrast, interbody spinal implant **1**, **101**, **101***a*, **201**, and **301** may be used as the final distractor and thus maintain the relative position of the vertebrae without the need for secondary instrumentation.

Certain embodiments collectively comprise a family of implants, each having a common design philosophy. These implants and the associated surgical technique have been designed to address at least the ten, separate challenges associated with the current generation of traditional anterior spinal fusion devices listed above in the Background section of this document.

Embodiments of the invention allow end-plate preparation with custom-designed rasps. These rasps preferably have a geometry matched with the geometry of the implant. The rasps conveniently remove cartilage from the endplates and remove minimal bone, only in the postero-lateral regions of the vertebral end-plates. It has been reported in the literature that the end-plate is the strongest in postero-lateral regions.

After desired annulotomy and discectomy, embodiments of the invention first adequately distract the disc space by inserting (through impaction) and removing sequentially larger sizes of very smooth distractors, which have been size matched with the size of the available implant **1**. Once adequate distraction is achieved, the surgeon prepares the end-plate with a rasp. There is no secondary instrumentation required to keep the disc space distracted while the implant **1**, **101**, **101***a*, **201**, and **301** is inserted, as the implant **1**, **101**, **101***a*, **201**, and **301** has sufficient mechanical strength that it is impacted into the disc space. In fact, the height of the implant **1**, **101**, **101***a*, **201**, and **301** is preferably about 1 mm greater than the height of the rasp used for end-plate preparation, to create some additional tension in the annulus by implantation, which creates a stable implant construct in the disc space.

The implant geometry has features which allow it to be implanted via any one of an anterior, antero-lateral, or lateral approach, providing tremendous intra-operative flexibility of options. The implant **1**, **101**, **101***a*, **201**, and **301** is designed such that all the impact loads are applied only to the titanium part of the construct. Thus, the implant **1**, **101**, **101***a*, **201**, and **301** has adequate strength to allow impact. The sides of the implant **1**, **101**, **101***a*, **201**, and **301** have smooth surfaces to allow for easy implantation and, specifically, to prevent binding of the implant **1**, **101**, **101***a*, **201**, and **301** to soft tissues during implantation.

The invention encompasses a number of different implant **1**, **101**, **101***a*, **201**, and **301** configurations, including a one-piece, titanium-only implant and a composite implant formed of top and bottom plates (components) made out of titanium. The surfaces exposed to the vertebral body are dual acid etched to allow for bony in-growth over time, and to provide resistance against expulsion. The top and bottom titanium plates are assembled together with the implant body that is injection molded with PEEK. The net result is a composite implant that has engineered stiffness for its clinical application. The axial load is borne by the PEEK component of the construct.

It is believed that an intact vertebral end-plate deflects like a diaphragm under axial compressive loads generated due to physiologic activities. If a spinal fusion implant is inserted in the prepared disc space via a procedure which does not destroy the end-plates, and if the implant contacts the end-plates only peripherally, the central dome of the end-plates can still deflect under physiologic loads. This deflection of the dome can pressurize the bone graft material packed inside the spinal implant, hence allowing it to heal naturally. The implant **1**, **101**, **101***a*, **201**, and **301** designed according to certain embodiments allows the vertebral end-plate to deflect and allows healing of the bone graft into fusion.

The roughened topography **80**, **180**, **180***a*, **280**, and **380** whether directly on the top/bottom surface of the implant **1**, **101**, **101***a*, **201**, and **301** or the integration plate **82**, **182**, **182***a*, **282**, and **382** reacts with contacting bone to promote biologic activities that facilitate fusion of bone to the implant **1**, **101**, **101***a*, **201**, and **301**. The implant **1**, **101**, **101***a*, **201**, and **301** is configured to resist movement after being seated in the joint space of the spine. To enhance movement resistance and provide additional stability under spinal loads in the body, the implant **1**, **101**, **101***a*, **201**, and **301** may comprise one or more anti-expulsion edges **8**, **108**, **108***a*, **208**, and **308** that tend to "dig" into the end-plates slightly and help to resist expulsion (FIGS. **18**A-**18**M). The anti-expulsion edges **8**, **108**, **108***a*, **208**, and **308** may be present on the top surface **10**, **110**, **110***a*, **210**, and **310**; the bottom surface **20**, **120**, **120***a*, **220**, and **320**; or both surfaces of the implant **1**, **101**, **101***a*, **201**, and **301**.

By way of example, FIG. **18**A shows an anti-expulsion edge **8** on the top surface **10** and bottom surface **20** of the anterior face **40** of the implant **1**. Each anti-expulsion edge **8** protrudes above the plane of the top surface **10** and bottom surface **20**, with the amount of protrusion increasing toward the anterior face **40** and the highest protrusion height P at the anterior-most edge of the top surface **10** or bottom surface **20**. As shown in FIG. **18**B, the protruding anti-expulsion edge **8** exposes a protruding surface **9**.

An anti-expulsion edge **8**, **108**, **108***a*, **208**, and **308** may be oriented toward the anterior portion **40**, **140**, **140***a*, **240**, and **340**, or the posterior portion **50**, **150**, **150***a*, **250**, and **350**, or either of the opposing lateral sides **30**, **130**, **130***a*, **230**, and **330**. The orientation of the anti-expulsion edge **8**, **108**, **108***a*, **208**, and **308** may depend on the intended orientation of the implant **1**, **101**, **101***a*, **201**, and **301** when it has been implanted between vertebrae in the patient.

FIGS. **18**C-**18**H show different perspective views of different embodiments of the implant **101** and **101***a*, with the amount of protrusion increasing toward the posterior face **150** and **150***a* and the highest protrusion height P at the posterior-most edge of the top surface **110** and **110***a* or bottom surface **120** and **120***a*. The protruding anti-expulsion edge **108** and **108***a* exposes a protruding surface **109** and **109***a*. FIGS. **18**I-**18**K show different perspective views of an embodiment of the implant **301**, with the amount of protrusion increasing toward one of the opposing lateral sides **330** and the highest protrusion height P at the most lateral edge of the top surface **310** or bottom surface **320**. The protruding anti-expulsion edge **308** exposes a protruding surface **309**. FIGS. **18**L and **18**M show different perspective views of an embodiment of

the implant **201**, with the amount of protrusion increasing toward the anterior portion **240** and the highest protrusion height P at the anterior-most edge of the top surface **210** or bottom surface **220**. The protruding anti-expulsion edge **208** exposes a protruding surface **209**.

In some preferred embodiments, the integration plate **82**, **182**, **182***a*, **282**, and **382** establishes the anti-expulsion edge **8**, **108**, **108***a*, **208**, and **308** for either or both of the top surface **10**, **110**, **110***a*, **210**, and **310** and bottom surface **20**, **120**, **120***a*, **220**, and **320** of the implant **1**, **101**, **101***a*, **201**, and **301**. Different integration plates **82**, **182**, **182***a*, **282**, and **382** may be used to establish a range of highest protrusion heights P.

When an integration plate **82** is used, it is preferred that the posterior portion **51** is substantially flush with the posterior portion edges of the implant **1**, for example, by having a thickness equivalent to the recess depth D. In other words, it is preferred that the junction of the posterior portion **51** of the integration plate **82** with the implant **1** not protrude higher than the plane of the top surface **10** or bottom surface **20** of the implant **1**. FIG. **19**A shows a cross-section of the implant **1** with an integration plate **82** having a protruding anti-expulsion edge **8**, and FIG. **19**B shows a close-up of the joint of the integration plate **82** and the top surface **10** of the implant **1**.

The posterior portion **51** of the integration plate **82** may comprise different edge features. FIGS. **20**A-D show non-limiting examples of possible configurations of the posterior portion **51** of the integration plate **82**, with FIGS. **20**B-D showing an enlarged view of the posterior portion **51** as encircled in FIG. **20**A. For example, the posterior portion **51** may have a substantially straight edge as shown in FIG. **20**A and FIG. **20**B, such that the edge of the posterior portion **51** aligns with a corresponding straight edge in the posterior portion **50** of the implant **1**. In some alternative aspects, the posterior portion **51** may have a substantially straight edge, and include a beveled edge or chamfer **51**C as shown in FIG. **20**C. In some alternative aspects, the posterior portion **51** may have a generally blunt nosed profile, including a generally rounded profile **51**D as shown in FIG. **20**D.

The implant **1**, **101**, **101***a*, **201**, and **301** may comprise a lordotic angle L, e.g., may be wedge-shaped to facilitate sagittal alignment. Thus, for example, the anterior portion **40**, **140**, **140***a*, **240**, and **340** of the implant **1**, **101**, **101***a*, **201**, and **301** may comprise a height that is larger than the height of the posterior portion **50**, **150**, **150***a*, **250**, and **350**. The lordotic angle L may be established by the implant **1**, **101**, **101***a*, **201**, and **301** itself, or may be established by the integration plate **82**, **182**, **182***a*, **282**, and **382** when combined with the implant **1**, **101**, **101***a*, **201**, and **301**.

The lordotic angle L of the implant **1** preferably closely approximates, or otherwise is substantially the same as, the angle of lordosis of the spine of the patient where the implant **1**, **101**, **101***a*, **201**, and **301** will be implanted. In some aspects, the integration plate **82**, **182**, **182***a*, **282**, and **382** increases the lordotic angle L by about 3% to about 5%, measured according to the angle of lordosis of a particular patient's spine. For example, as shown in FIG. **21**, the anti-expulsion edge **8** protrudes to a height sufficient to increase the overall height H of the anterior portion **40** of the implant **1** such that implant **1** has a lordotic angle L that is about 3% to about 5% greater than the patient's angle of lordosis.

The implant **1**, **101**, **101***a*, **201**, and **301** may have a lordotic angle L about 3%, about 3.3%, about 3.5%, about 3.7%, about 4%, about 4.3%, about 4.5%, about 4.7%, or about 5% greater than the patient's angle of lordosis, though percentages greater than 5% or lesser 3% are possible. The increase of about 3% to about 5% preferably results from the combination of the protruding height of the integration plate **82**, **182**, **182***a*, **282**, and **382** on the top portion **10**, **110**, **110***a*, **210**, and **310** and bottom portion **20**, **120**, **120***a*, **220**, and **320** of the implant **1**, **101**, **101***a*, **201**, and **301**.

The expulsion-resistant edge **8**, **108**, **108***a*, **208**, and **308** may comprise an anti-expulsion edge angle E, for example, as shown in FIG. **22** with respect to the implant **1**. The anti-expulsion edge angle E may be from about 80 degrees to about 100 degrees. In preferred aspects, the anti-expulsion edge angle E may be measured by taking into account the lordosis angle L of the implant **1**, **101**, **101***a*, **201**, and **301**. In highly preferred aspects, the anti-expulsion edge angle E is measured by subtracting half of the lordotic angle L from 90 degrees. For example, where the lordosis angle L of the implant **1**, **101**, **101***a*, **201**, and **301** is 12 degrees, the anti-expulsion edge angle E is 84 degrees (90−(12×0.5)). The anti-expulsion edge angle E may be about 80 degrees, about 81 degrees, about 82 degrees, about 83 degrees, about 84 degrees, about 85 degrees, about 86 degrees, about 86.5 degrees, about 87 degrees, about 88 degrees, or about 89 degrees.

The top and bottom surfaces of the implant may be made out of titanium and are dual acid etched. The dual acid etching process creates a highly roughened texture on these surfaces, which generates tremendous resistance to expulsion. The width of these dual acid etched surfaces is very broad and creates a large area of contact with the vertebral end-plates, further increasing the resistance to expulsion.

The implant **1** according to certain embodiments of the invention has a large foot-print, and offers several sizes. Because there is no secondary instrument required to maintain distraction during implantation, all the medial-lateral (ML) exposure is available as implantable ML width of the implant. This feature allows the implant to contact the vertebral end-plates at the peripheral apophyseal rim, where the end-plates are the strongest and least likely to subside.

Further, there are no teeth on the top and bottom surfaces (teeth can create stress risers in the end-plate, encouraging subsidence). Except for certain faces, all the implant surfaces have heavily rounded edges, creating a low stress contact with the end-plates. The wide rim of the top and bottom surfaces, in contact with the end-plates, creates a low-stress contact due to the large surface area Finally, the implant construct has an engineered stiffness to minimize the stiffness mismatch with the vertebral body which it contacts.

The implant **1** according to certain embodiments of the invention has a large foot-print. In addition, titanium provides high strength for a small volume. In combination, the large foot-print along with the engineered use of titanium allows for a large volume of bone graft to be placed inside the implant.

It is believed that an intact vertebral end-plate deflects like a diaphragm under axial compressive loads generated due to physiologic activities. If a spinal fusion implant is inserted in the prepared disc space via a procedure which does not destroy the end-plate, and if the implant contacts the end-plates only peripherally, the central dome of the end-plates can still deflect under physiologic loads. This deflection of the dome can pressurize the bone graft material packed inside the spinal implant, hence allowing it to heal naturally. The implant **1** according to certain embodiments of the invention allows the vertebral end-plate to deflect and facilitates healing of the bone graft into fusion.

The top and bottom surfaces of the implant **1** according to certain embodiments of the invention are made of titanium and are dual acid etched. The dual acid etched surface treatment of titanium allows in-growth of bone to the surfaces. Hence, the implant **1** is designed to incorporate with the

vertebral bone over time. It may be that the in-growth happens sooner than fusion. If so, there may be an opportunity for the patients treated with the implant **1** to return to normal activity levels sooner than currently recommended by standards of care.

Even the titanium-only embodiment of the invention has been designed with large windows to allow for radiographic evaluation of fusion, both through AP and lateral X-rays. A composite implant minimizes the volume of titanium, and localizes it to the top and bottom surfaces. The rest of the implant is made of PEEK which is radiolucent and allows for free radiographic visualization.

Although illustrated and described above with reference to certain specific embodiments and examples, the invention is nevertheless not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the spirit of the invention. It is expressly intended, for example, that all ranges broadly recited in this document include within their scope all narrower ranges which fall within the broader ranges. In addition, features of one embodiment may be incorporated into another embodiment.

What is claimed:

1. An interbody spinal implant, comprising:

a body having a top surface, a bottom surface, opposing lateral sides, opposing anterior and posterior portions, a substantially hollow center, and a single vertical aperture extending from the top surface to the bottom surface, and having varying width and maximum width at its center, wherein a portion of the top surface of the body, and optionally the bottom surface of the body, is recessed and comprises a plurality of vertical holes along the periphery of the vertical aperture, and the non-recessed portion of the top surface and, if the bottom surface is recessed, the non-recessed portion of the bottom surface comprises a blunt and radiused portion; and

a first integration plate, and optionally a second integration plate, comprising a top surface having a roughened surface topography adapted to grip bone and inhibit migration of the implant, a bottom surface having a plurality of vertical posts, opposing lateral sides, opposing anterior and posterior portions, and a single vertical aperture extending from the top surface to the bottom surface of the integration plate, aligning with the single vertical aperture of the body, and defining a transverse rim with a varying width;

wherein the entire bottom surface of the first integration plate is inserted into the recessed portion of the top surface of the body and the plurality of posts are inserted into the plurality of holes, thereby affixing the first integration plate to the body, and if a second integration plate is present, the entire bottom surface of the second integration plate is inserted into the recessed portion of the bottom surface of the body and the plurality of posts are inserted into the plurality of holes, thereby affixing the second integration plate to the body.

2. The interbody spinal implant of claim **1**, wherein the body and the first integration plate are each comprised of a metal, and if a second integration plate is present, the second integration plate is comprised of a metal.

3. The interbody spinal implant of claim **2**, wherein the metal comprises titanium.

4. The interbody spinal implant of claim **1**, wherein the body is comprised of a non-metal polymer and the first integration plate is comprised of a metal, and if a second integration plate is present, the second integration plate is comprised of a metal.

5. The interbody spinal implant of claim **4**, wherein the non-metal polymer is selected from the group consisting of polyetherether-ketone, hedrocel, and ultra-high molecular weight polyethylene.

6. The interbody spinal implant of claim **1**, wherein the body is comprised of a composite of a metal and a non-metal polymer selected from the group consisting of polyetherether-ketone, hedrocel, and ultra-high molecular weight polyethylene.

7. The interbody spinal implant of claim **1**, wherein the body and the first integration plate are generally oval-shaped in transverse cross-section, and if a second integration plate is present, the second integration plate is generally oval-shaped in transverse cross-section.

8. The interbody spinal implant of claim **1**, wherein the body and the first integration plate are generally rectangular-shaped in transverse cross-section, and if a second integration plate is present, the second integration plate is generally rectangular-shaped in transverse cross-section.

9. The interbody spinal implant of claim **1**, wherein the body and the first integration plate are generally curved-shaped in transverse cross-section, and if a second integration plate is present, the second integration plate is generally curved-shaped in transverse cross-section.

10. The interbody spinal implant of claim **1**, wherein the anterior portion of the body or the posterior portion of the body comprises an opening for achieving one or more of the following functions: being adapted to engage a delivery device, facilitating delivery of bone graft material to the substantially hollow center, enhancing visibility of the implant, and providing access to bone graft material.

11. The interbody spinal implant of claim **1**, further comprising bone graft material disposed in the substantially hollow center of the body and adapted to facilitate the formation of a solid fusion column within the spine.

12. The interbody spinal implant of claim **11**, wherein the bone graft material is cancellous autograft bone, allograft bone, demineralized bone matrix (DBM), porous synthetic bone graft substitute, bone morphogenic protein (BMP), or a combination thereof.

13. The interbody spinal implant of claim **1**, wherein the at least one of an anterior, posterior, or lateral section of the recessed portion of the top surface of the body, is recessed to a depth corresponding to the thickness of the first integration plate, and if the bottom surface of the body is recessed, at least one of an anterior, posterior, or lateral section of the recessed portion of the bottom surface of the body is recessed to a depth corresponding to the thickness of the second integration plate.

14. The interbody spinal implant of claim **1**, wherein the implant comprises a lordotic angle adapted to facilitate alignment of the spine.

15. The interbody spinal implant of claim **1**, wherein the interbody spinal implant is adapted to be inserted into a prepared disc space via a procedure which does not destroy the vertebral end-plates or to contact the vertebral end-plates only peripherally, allowing the intact vertebral end-plates to deflect like a diaphragm under axial compressive loads generated due to physiologic activities and pressurize the bone graft material disposed inside the spinal implant.

16. The interbody spinal implant of claim **1**, wherein at least one of the anterior and posterior portions of the first integration plate comprise an anti-expulsion edge to resist pullout of the implant from the spine of a patient into which

the implant has been implanted, and if a second integration plate is present, at least one of the anterior and posterior portions of the second integration plate comprise an anti-expulsion edge to resist pullout of the implant from the spine of a patient into which the implant has been implanted.

17. The interbody spinal implant of claim **1**, wherein the anterior portion of the first integration plate has a greater thickness than the thickness of the posterior portion of the first integration plate, and if a second integration plate is present, the anterior portion of the second integration plate has a greater thickness than the thickness of the posterior portion of the second integration plate.

18. The interbody spinal implant of claim **1**, wherein the posterior portion of the first integration plate has a greater thickness than the thickness of the anterior portion of the first integration plate, and if a second integration plate is present, the posterior portion of the second integration plate has a greater thickness than the thickness of the anterior portion of the second integration plate.

19. The interbody spinal implant of claim **1**, wherein one of the opposing lateral sides of the first integration plate has a greater thickness than the other of the opposing lateral sides of the first integration plate, and if a second integration plate is present, one of the opposing lateral sides of the second integration plate has a greater thickness than the other of the opposing lateral sides of the second integration plate.

20. The interbody spinal implant of claim **1**, wherein the body further comprises a transverse aperture.

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